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| **Report No.** Comment of NB 1023  **On review of the manufacturer's application and documentation of a medical device** |
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| Application | | | | |
| Now application | Extension of validity of certificate (Recertification) | OBL manufacturer | Transfer from another NB | Change |
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| In case of a change, please specify your request and check which parts of this report will be updated upon your request. | | | | |
| Manufacturer’s comment | | | | |
| ***Fill in only in case of a modification (to be filled in by the manufacturer).***  4  5  6  7  8  9  10  11  12  13  14  15  16  17  18  19  20  Annex 1  ***\**** ***Note: Even in the case of a change, provision of a complete technical documentation is required, not only parts that have been updated as a result of the change!!!*** | | | | |
| Instructions to fill in the form | | | | |
| * It is necessary to fill in all relevant sections of this form (except sections intended for the NB 1023 assessor). If the information is provided in other supporting documents (format doc, docx, pdf, etc.), please provide an exact reference to that document | | | | |
| * Please submit an unsigned version of the request in the .doc / .docx format as well as a signed copy (a scan or a secured pdf) - a scan of signed section 3 of this report   ***Procedure for creation of a report in PDF format:***   1. ***Print out only the Chapter 3 (Applicant's Statement) of the filled-in report*** 2. ***Sign and scan the Applicant's Statement*** 3. ***Save the message in \* .doc / \*.docx format as well as in pdf format. Use the File - Save As menu and in the dialog box select out of the offer "Save As Type" the "PDF Format (\* .pdf)***   ***In the pdf version of the message, replace Chapter 3 with the signed Applicant's Statement.*** | | | | |
| * The application and supporting documents referred to in the individual parts of this report shall be submitted in electronic or printed form as follows (documents in a printed form are not required) | | | | |
| CD  Memory media  ITC web store (<http://212.111.4.154:8082/intranet/ulozto/indexEN.php>)  Other protected web store  Correspondence address for printed documents):  Institut pro testování a certifikaci, a. s.  třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic | | | | |
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| Checklist of the Applicant‘s Documentation | | | | |
| Filled in Report on review the manufacturer's application (unsigned version in .doc /.docx format) | | | | |
| Filled in Report on review the manufacturer's application (scan of signed Section 3 of this form (pdf)) | | | | |
| QMS certificate(s) of the manufacturer (as well as of critical suppliers, if applicable) | | | | |
| Draft of the Declaration of Conformity | | | | |
| Draft of the Label and the Instruction for Use | | | | |
| Overview of fulfilling the essential requirements | | | | |
| Declared functional capability | | | | |
| Risk management documentation | | | | |
| Validation of the sterilization process in case of sterile products or products intended to be sterilized before use | | | | |
| Documents related to product stability (if relevant) | | | | |
| Documents related to biocompatibility of the product (if relevant) | | | | |
| Testing of electrical safety, validation of SW, usability determination (if relevant) | | | | |
| Tests of simulated use (if relevant) | | | | |
| Clinical Assessment Report and other supporting documents containing clinical data | | | | |
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| In case of transfer from another NB, it is necessary to provide additionally | | | | |
| Copy of the valid EC certificate or if applicable EC design examination certificate | | | | |
| Certificate transfer plan (schedule) | | | | |
| Contact details of the existing Notified Body  Proposal for a tripartite agreement among the existing Notified Body, the manufacturer and NB 1023 | | | | |
|  | | | | |
| For OBL manufacturers additionally | | | | |
| Copies of EC certificate(s) of the OEM manufacturer | | | | |
| Proof of identity of the products covered by this application with products covered by the OEM manufacturer's certificates | | | | |
| Agreement between the OBL and the OEM manufacturer (including the responsibilities of the concerned parties)  Complete technical documentation of the OEM manufacturer | | | | |

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| Applicant's Statement | | | |
| * The application is filled in correctly and does not contain false or misleading information * We have not submitted an application to assess a compliance of this medical device in parallel at another notified body * We agree that samples of the product (if requested) will not be returned after the tests. * We have signed the General Framework Agreement (GFA) with ITC. * Neither our company nor our employees have a relationship with NB 1023 ITC, which might jeopardize an independence and impartiality of ITC's decision-making. The only type of service that the ITC provides to us is the conformity assessment and product testing (if requested). * This medical device does not contain, as an integral part, a substance or a derivative of human blood. * This medical device is not manufactured using tissues of animal origin according to Commission Regulation No. 722/2012. * This medical device  contains  does not contain, as an integral part, a substance that may be considered to be a drug product within the meaning of Article 1 of Directive 2001/83 / EC (Article 2 of Act No. 378/2007 Coll.) and which may affect a body by a complementary effect to an effect of the device. * The manufacturer undertakes to fulfil all obligations arising out of the approved quality system. * The manufacturer undertakes to maintain the quality system in usable and efficient condition. * The manufacturer undertakes to introduce and update a systematic procedure for evaluation of the experience gained with the manufactured devices, including the provisions stated in Annex X to Directive 93/42/EEC, and will carry out appropriate corrective action by a suitable means. A part of this obligation includes the obligation for the manufacturer to notify the competent authorities on the following adverse reactions as soon as he becomes aware of them: * any failure or deterioration of the characteristics and/or functional suitability of the device and any inaccuracy in the instructions for use that may result or might have resulted in death of the patient or user or to a serious deterioration in their state of health; * any technical or medical reason that is related to the characteristics or functional suitability of the device, and which forces the manufacturer to systematically withdraw the devices of such type from the market. | | | |
|  | | | |
| Signature of the manufacturer: |  | | Date: insert date |
| Name of representative of the manufacturer: | Comment of the manufacturer | |  |
| Position in organisation of the manufacturer: | Comment of the manufacturer | | |
| Contact person (only in case it differs from the representative of the manufacturer): | Comment of the manufacturer | | |
| e-mail: Comment of the manufacturer | Phone: | Comment of the manufacturer | |

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| Identification of the Manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| Name of the manufacturer | | | | | | Comment of the manufacturer | | | | | | | | | | | | | | | | | | |
| Address of the residence | | | | | | Comment of the manufacturer | | | | | | | | | | | | | | | | | | |
| Extract from the Commercial Register - please refer to a part of the technical documentation containing the required extract: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| Addresses of the production sites (in case of outsourcing also the company name) | | | | | | | | | | | | | | | | | | | | | | | | |
| * assembly / production | | | | | | Comment of the manufacturer | | | | | | | | | | | | | | | | | | |
| * sterilization | | | | | | Comment of the manufacturer | | | | | | | | | | | | | | | | | | |
| * output control / final testing | | | | | | Comment of the manufacturer | | | | | | | | | | | | | | | | | | |
| * packaging | | | | | | Comment of the manufacturer | | | | | | | | | | | | | | | | | | |
| * warehouse of finished products | | | | | | Comment of the manufacturer | | | | | | | | | | | | | | | | | | |
| Other manufacturing sites (if relevant) | | | | | | Comment of the manufacturer | | | | | | | | | | | | | | | | | | |
| Name and address of the OEM manufacturer (if applicable) | | | | | | Comment of the manufacturer | | | | | | | | | | | | | | | | | | |
| Name of the authorized representative in EU (if relevant) | | | | | | Comment of the manufacturer | | | | | | | | | | | | | | | | | | |
| Address of the authorized representative (if relevant) | | | | | | Comment of the manufacturer | | | | | | | | | | | | | | | | | | |
| As a part of the submitted documentation, is there a contract with a authorised representative in EU? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Not, please substantiate: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer. | | | | | | | | | | | | | | | | | | | | | | | | |
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| NB 1023 review  Compliance of registration data on the application with GFA  Provided Quality System Certificates related to the production of the MD and their validity  Contract of the manufacturer with authorized representative  Subcontractors included in the manufacturing process of the MD | | | | | | | | | | | | | | | | | | | | | | | | |
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| **NB 1023 review** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of assessor of the technical documentation | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the internal clinic (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of another assessor (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | |  | | | | | | |
| Finding | | | Yes | | | | | | | No | | | | | | | | Number of finding: Enter the number of finding | | | | | | |
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| Product Information | | | | | | | | | | | | | | | | | | | | | | | | |
| Group of medical devices | | | | | | Comment of the manufacturer | | | | | | | | | | | | | | | | | | |
| Trade names (if relevant) | | | | | | Comment of the manufacturer | | | | | | | | | | | | | | | | | | |
| Models / catalogue numbers | | | | | | Comment of the manufacturer | | | | | | | | | | | | | | | | | | |
| Risk class of the medical device | | | | | | Comment of the manufacturer | | | | | | | | | | | | active | | | | sterile | | |
| GMDN code (if granted) / eventually other ID code of the MD | | | | | | Comment of the manufacturer | | | | | | | | | | | | | | | | | | |
| ***In the case a subject of this application is more product groups and/or models and/or variants, it is necessary to submit a separate document, which shall uniquely identify the individual products and/or models and/or variants (a document in \*.doc, eventually \*.docx, xls, xlsx formats).*** | | | | | | | | | | | | | | | | | | | | | | | | |
| Enter the title and number of the document: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer. | | | | | | | | | | | | | | | | | | | | | | | | |
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| NB 1023 review  Group of medical devices  Comparison of models of MD with data in the technical documentation  Declaration on conformity | | | | | | | | | | | | | | | | | | | | | | | | |
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| **NB 1023 review** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of assessor of the technical documentation | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the internal clinic (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of another assessor (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
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| Finding | | | Yes | | | | | | | No | | | | | | | | Number of finding: Enter the number of finding | | | | | | |
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| Description of the Product | | | | | | | | | | | | | | | | | | | | | | | | |
| ***Description of the product (full product description demonstrating that a given product meets the definition of a medical device and falls within the MDD)*** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| Provide the title and number of the document: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
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| NB 1023 review  Description of the product  The product is a medical device according to Article 1, Paragraph. 2, Letters a) and b) of the MDD) | | | | | | | | | | | | | | | | | | | | | | | | |
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| **NB 1023 review** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of assessor of the technical documentation | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the internal clinic (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of another assessor (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Finding | | | Yes | | | | | | | No | | | | | | | | Number of finding: Enter the number of finding | | | | | | |
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| Intended Purpose of the Product | | | | | | | | | | | | | | | | | | | | | | | | |
| ***Full description of the intended purpose of the product*** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| Provide the title and number of the document: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
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| NB 1023 review  The intended purpose is unambiguously defined  The intended purpose is in accordance with marking of the product  The intended purpose corresponds to the classification of the product | | | | | | | | | | | | | | | | | | | | | | | | |
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| **NB 1023 review** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of assessor of the technical documentation | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the internal clinic (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of another assessor (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Finding | | | Yes | | | | | | | No | | | | | | | | Number of finding: Enter the number of finding | | | | | | |
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| Categorization and Classification of the Product | | | | | | | | | | | | | | | | | | | | | | | | |
| Class | III  IIb  IIa  Is  Im | | | | | | | | | | | | | | | | | Rule(s) | | | | | Comment of the manufacturer. | |
| Justify the classification: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer. | | | | | | | | | | | | | | | | | | | | | | | | |
| Selected procedure of assessment of compliance according to MDD: | | | | | | | | | | | | | | | | | | | | | | | | |
| Annex II without point 4 (full Quality management system) | | | | Annex II, point 4 (ES design examination) | | | | | | Annex V (System of production quality) | | | | | | | | | Annex VI (System of product quality) | | | | | |
| Provide the title and number of the document: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
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| NB 1023 review  Applied rule(s)  The intended purpose of the product corresponds with the classification of the product  Meets the classification –  Yes  No  Correctness of the selected conformity assessment procedure (according to Directive 93/42/EEC, as amended) | | | | | | | | | | | | | | | | | | | | | | | | |
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| **NB 1023 review** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of assessor of the technical documentation | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the internal clinic (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of another assessor (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Finding | | | Yes | | | | | | | No | | | | | | | | Number of finding: Enter the number of finding | | | | | | |
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| Previous Approvals of the Product | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Has the product been already approved according to other legal regulations (e.g. ANVISA, FDA 510(k)), KFDA, PLA GMP, etc.) | | | | | | | | | | | | | | Yes | | | | | | | | No | | |
| If Yes, please state a name and number of relevant approval and a reference to a part of the technical documentation, where the relevant approval can be found: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is the concerned product affixed with a CE mark with a number of another Notified Body? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, a transfer from another Notified Body is concerned and it is necessary to provide these documents: | | | | | | | | | | | | | | | | | | | | | | | | |
| * Copy of valid EC certificate | | | | | | | | | | | | | | | | | | | | | | | | |
| * Transfer plan of the certificate (e.g. planned communication with the existing Notified Body, time schedule including date from when the product will cease to bear the CE marking with the identification number of the existing Notified Body) | | | | | | | | | | | | | | | | | | | | | | | | |
| * Contact data of the present Notified body * Tripartite agreement | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is the concerned product already assessed according to the requirements of MDD and placed to market by another manufacturer | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, the OBL-OEM relationship is concerned and it is necessary to provide the following documents: | | | | | | | | | | | | | | | | | | | | | | | | |
| * Copy of a valid ES certificate | | | | | | | | | | | | | | | | | | | | | | | | |
| * Proof of identity of the products covered by this application with the products covered by the certificate(s) of the OEM manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * Contract between OBL and OEM manufacturer, including determination of responsibilities for fields of | | | | | | | | | | | | | | | | | | | | | | | | |
| * Changes in the design and a way of notifying them | | | | | | | | | | | | | | | | | | | | | | | | |
| * + Vigilance cases and solving of complaints | | | | | | | | | | | | | | | | | | | | | | | | |
| * + Changes in quality system of OEM manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * + Changes in production environment (affecting a quality of the final product) and a way of notifying them | | | | | | | | | | | | | | | | | | | | | | | | |
| * + Responsibility for release of a sterile product | | | | | | | | | | | | | | | | | | | | | | | | |
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| NB 1023 review  Previous approvals  Transfer from another Notified body:  valid certificate  plan od transfer of the certificate  communication with a present Notified Body  OBL process  OEM certificate  OBL-OEM contract  Responsibilities of OEM and OBL manufacturers | | | | | | | | | | | | | | | | | | | | | | | | |
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| **NB 1023 review** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of assessor of the technical documentation | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the internal clinic (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of another assessor (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Finding | | | Yes | | | | | | | No | | | | | | | | Number of finding: Enter the number of finding | | | | | | |
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| Functional Suitability and Solving of Complaints | | | | | | | | | | | | | | | | | | | | | | | | |
| ***Provide the required information for the product if it has already been placed on the market (EU or elsewhere). If not, go to chapter 11.*** | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is there a history of the assessed product (post marketing reports, overview of solving of adverse events, claims and complaints) | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Time period of provided data: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Total number of sold pieces: | | | | | | | | | | | | | | | | Comment of the manufacturer | | | | | | | | |
| Total number of complaints and claims: | | | | | | | | | | | | | | | | Comment of the manufacturer | | | | | | | | |
| Total number of adverse events: | | | | | | | | | | | | | | | | Comment of the manufacturer | | | | | | | | |
| Total numbers of issued safety notifications: | | | | | | | | | | | | | | | | Comment of the manufacturer | | | | | | | | |
| 1. Are the following information included in the provided documentation? | | | | | | | | | | | | | | | | | | | | | | | | |
| a summary table of complaints containing the number of complaints and a percentage share of them from the total number of sold items | | | | | | | | | | | | | | | | | | | | | | | | |
| categorization of complaints - justified/non-justified, related to the functional capability of the product, clinical use or labelling, etc. | | | | | | | | | | | | | | | | | | | | | | | | |
| copies of reports on solving adverse events (if relevant) | | | | | | | | | | | | | | | | | | | | | | | | |
| Provide the title and number of the document(s), where the above-mentioned information can be found: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| If any from the above-mentioned points (part 4 of this section) has not been fulfilled, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | |  | | | | | | |  | | | | | | | |  | | | | | | |
| NB 1023 review  Provision of all required data  Way of solving of the adverse events | | | | | | | | | | | | | | | | | | | | | | | | |
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| **NB 1023 review** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of assessor of the technical documentation | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the internal clinic (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of another assessor (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Finding | | | Yes | | | | | | | No | | | | | | | | Number of finding: Enter the number of finding | | | | | | |
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| Product Labelling and Instructions for Use | | | | | | | | | | | | | | | | | | | | | | | | |
| ***It is necessary to submit the draft of labels and instructions for use in Czech, Slovak or English language.*** | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Provide the reference(s) to the part of the technical documentation, which contains a draft of the labels (on the product, on the packaging, eventually on the shipping packaging) and of the instructions for use | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer. | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Provide a reference to the procedure for translation and control of correctness of the translation of labels and instructions for use into other language versions | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer. | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Specify the standards that have been used to prove the requirements for content of the product labelling and instructions for use | | | | | | | | | | | | | | | | | | | | | | | | |
| |  |  |  | | --- | --- | --- | | **Marking of a standard** | **Year of issue of the standard** | **Name of the standard** | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer |   ***Add additional rows if necessary (place the cursor on an end of the table row and Enter).*** | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Have there been provided the electronic instructions? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If yes, please provide evidence that the instructions meet the requirements of Commission Regulation (EU) No. 207/2012 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. If the instructions for use do not form part of the technical documentation (only for products of Class IIa or below), please justify an enabling of its absence. | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is an active medical device concerned? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, were taken in account: | | | | | | | | | | | | | | | | | | | | | | | | |
| * the requirements of EN 60601-1, concerning the marking and information stated in the instructions for use? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * + the requirements of EN 60601-1-2 concerning the marking and information stated in the instructions for use? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * Have been applied any other standards extending the labelling requirements of the product and the information stated in the instructions for use? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please specify what standards are concerned: | | | | | | | | | | | | | | | | | | | | | | | | |
| |  |  |  | | --- | --- | --- | | **Marking of a standard** | **Year of issue of the standard** | **Name of the standard** | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | | Comment of the manufacturer | Comment of the manufacturer. | Comment of the manufacturer | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer |   ***Add additional rows if necessary (place the cursor on an end of the table row and Enter).*** | | | | | | | | | | | | | | | | | | | | | | | | |
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| NB 1023 review  Review of the labels  The provided labels contain information required by point 13 of the Essential Requirements, in particular by subsection 13.3  Review of IfU  The provided Instructions for Use contain information required by point 13 of the Essential Requirements, in particular by subsection 13.6  Symbols and marking on labels of the active medical device according to Table D1 of EN 60601-1:2006 (including the requirements of the standards of EN 60601-2-XX series)  Review of topicality of the applied standards | | | | | | | | | | | | | | | | | | | | | | | | |
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| **NB 1023 review** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of assessor of the technical documentation | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the internal clinic (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of another assessor (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Finding | | | Yes | | | | | | | No | | | | | | | | Number of finding: Enter the number of finding | | | | | | |
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| Essential Requirements and Applied Standards | | | | | | | | | | | | | | | | | | | | | | | | |
| ***Please indicate how the essential requirements (Annex I) of the Medical Devices Directive 93/42/EEC are fulfilled.*** | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Submit the completed Checklist of Essential Requirements, including the assignment of applicable standards and corresponding parts of the technical documentation to the individual requirements demonstrating their fulfillment. For requirements that have not been applied, an appropriate justification shall be included in the checklist. Provide the name and number of the requested document. | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Were the harmonized standards used to demonstrate compliance with the essential requirements? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please specify, which standards are concerned: | | | | | | | | | | | | | | | | | | | | | | | | |
| |  |  |  | | --- | --- | --- | | **Marking of a standard** | **Year of issue of the standard** | **Name of the standard** | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer |   ***Add additional rows if necessary (place the cursor on an end of the table row and Enter).*** | | | | | | | | | | | | | | | | | | | | | | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Were the non-harmonized standards or other recommending documents (MEDDEV, TS ant others) used to demonstrate compliance with the essential requirements? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, specify, which standards and recommending documents are concerned: | | | | | | | | | | | | | | | | | | | | | | | | |
| |  |  |  | | --- | --- | --- | | **Marking of a standard/document** | **Year of issue of the standard** | **Name of the standard** | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer |   ***Add additional rows if necessary (place the cursor on an end of the table row and Enter).*** | | | | | | | | | | | | | | | | | | | | | | | | |
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| NB 1023 review  Essential Requirements and their fulfilment  References to documents used for fulfilment of essential requirements  Applied harmonized standards, eventually justification of not using them (if relevant)  Applied non-harmonized standards and recommending documents | | | | | | | | | | | | | | | | | | | | | | | | |
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| **NB 1023 review** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of assessor of the technical documentation | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the internal clinic (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of another assessor (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Finding | | | Yes | | | | | | | No | | | | | | | | Number of finding: Enter the number of finding | | | | | | |
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| Risk Analysis | | | | | | | | | | | | | | | | | | | | | | | | |
| ***Provide all documents relevant to the risk management of the assessed product. If a part of the product is an active pharmaceutical ingredient, additional information may be required, see Annex I to this report.*** | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Submit a reference to a section of the technical documentation (title and document number) that contains the Risk Analysis, Risk Management Report and other supporting documents | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is the risk analysis prepared according to EN ISO 14971 version? Comment of the manufacturer | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| Is it the most current version of the standard? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If No, please justify | | | | | | | | | | |  | | | |  | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | |  | | | |  | | | | | | | | | |
| 1. Specify a team of experts involved in identifying the risks associated with the product at all stages of its life cycle (including their qualification). If the requested information is part of another document, provide the name and number of the document. | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Provide an evidence of qualifications (CV) of individual members of the risk analysis team. | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. How the risks are transferred to the instructions for use - Specify an overview of risks that were reflected in the instructions for use (contraindications, safety notifications, warnings, etc.). | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. If the active products are concerned, has the risk management documentation been extended by risk management requirements for active products and/or software? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
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| NB 1023 review  Signed and dated conclusions, concerning the residual risks  Residual risks are acceptable in relation to the purpose of use and benefits of the product for a patient  Compliance with the requirements of EN ISO 14971 (applied version), appropriately chosen methodology of identification and risk reduction  Suitability of the team for identification of risks in individual life stages of products  Clinical risks have been identified by a qualified person  The contraindications listed in the instructions for use come out of the risk management documentation  Risk reduction measures are included in the instructions for use (if relevant)  Acceptability of risk analysis in relation to the intended use and benefits of the product  Setting of requirements for ongoing update of risk management documentation  Solutions adopted by the manufacturer are in compliance with the safety principles, taking into account the generally accepted state of science and technology | | | | | | | | | | | | | | | | | | | | | | | | |
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| **NB 1023 review** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of assessor of the technical documentation | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the internal clinic (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of another assessor (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Finding | | | Yes | | | | | | | No | | | | | | | | Number of finding: Enter the number of finding | | | | | | |
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| Design and Construction of the Product | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Production diagram and description of the individual stages of the manufacturing process. Provide the title and number of the document. | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Drawing documentation describing the shape and dimensions of the components (wiring diagrams in case of active MD), including design of packaging (primary/secondary). Provide the title and number of the document. | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Critical components, components and materials, used for manufacturing the medical device. Provide the title and number of the document. | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. List of suppliers of critical parts of the product and/or parts of the manufacturing process (including information on whether the relevant supplier has a certified quality system). Provide the title and number of the document (including the suppliers' quality system certificates, if relevant). | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is the device intended to be used in combination with other devices or equipment? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, provide a title and number of the document, proving that the used combination does not impair a stated functionality of the device. | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is a device with measuring function concerned? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, provide a title and number of the document showing that the product provides a sufficient accuracy and stability within the limits of accuracy with regard to its intended purpose and its metrological continuity is ensured. | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
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| NB 1023 review  Description of manufacturing process  Design documentation  Used materials and parts  Critical suppliers of materials and services (parts of manufacturing process)  Using in combination (if relevant)  Measuring function and metrological continuity (if relevant) | | | | | | | | | | | | | | | | | | | | | | | | |
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| **NB 1023 review** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of assessor of the technical documentation | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the internal clinic (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of another assessor (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Finding | | | Yes | | | | | | | No | | | | | | | | Number of finding: Enter the number of finding | | | | | | |
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| Sterilization | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is the product marketed in a sterile state or is it intended to be sterilized prior to use? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| **If Not, go to the Section 16** | | | | | | | | | | | | | | | | | | | | | | | | |
| ***If the product is delivered in a sterile state or it is intended for sterilization prior to use, please provide the reports and protocols related to validation of the sterilization process and fill in the required information into the table below.*** | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. f a new product or a certificate transfer are concerned, please specify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Performing of an initial validation of sterilization process, date Click here and enter the date. | | | | | | | | | | | | | | | | | | | | | | | | |
| Performing of the latest process re-validation (if more than 1 year has elapsed from the initial validation), date Click here and enter the date. | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Overview of information on sterilization | | | | | | | | | | | | | | | | | | | | | | | | |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Product** | **Catalogue number** | **Sterilization method** | **Place of sterilization** | **Number of report/protocol** | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer |   ***Add more rows if needed***. | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is the product sterilized by Ethylene oxide? If No, go to point 7 of this section. | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| 1. Has a compliance with requirements of EN ISO 10993-7 (as amended) been proven? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Has a compliance with requirements of EN ISO 11135 (as amended) been proven? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| Categorize the product according to the duration of contact (see the requirements of EN ISO 10993-7): | | | | | | | | | | | | | | | | | | | | | | | | |
| limited exposure | | | | | | | | | | | | | | | | | | | | | | | | |
| prolonged exposure | | | | | | | | | | | | | | | | | | | | | | | | |
| permanent contact | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is the product sterilized by irradiation? If No, go to point 9 of this section. | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| 1. Has a compliance with requirements of EN ISO 11137 (as amended) been proven? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| Gamma irradiation | | | | | | | | | | | | | Beta irradiation | | | | | | | | | | | |
| What method of determination of the dose has been used? | | | | | | | | | | | | | | | | | | | | | | | | |
| VDMAX25/VDMAX15 | | | | | | | Method 1 | | | | | | | | | | Method 2 | | | | | | | |
| 1. Is the product sterilized by moist heat? If No, go to point 12 of this section. | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| 1. Has a compliance with requirements of EN ISO 17665 (as amended) been proven? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. What kind of operation cycle is being used? | | | | | | | | | | | | | | | | | | | | | | | | |
| Saturated steam - ventilated systems | | | | | | | | | Saturated steam - forced air removal | | | | | | | | | | | | | | | |
| Operation cycles working with increased air pressure | | | | | | | | | others | | | | | | | | | | | | | | | |
| If other, please specify in more detail: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. If a method other than the above is used, please describe in detail the used method and specify the applicable legislative requirements (standards, technical specifications, etc.). | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | |  | | | | | | |  | | | | | | | |  | | | | | | |
| NB 1023 review  Compliance with requirements of the applied sterilization standard  In a case of EO, a compliance with requirements of EN ISO 10993-7 has been verified | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | |  | | | | | | | | | | | | | | | | | | |
| **NB 1023 review** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of assessor of the technical documentation | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the internal clinic (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of another assessor (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Finding | | | Yes | | | | | | | No | | | | | | | | Number of finding: Enter the number of finding | | | | | | |
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| Stability | | | | | | | | | | | | | | | | | | | | | | | | |
| ***Provide all reports and protocols necessary to prove a stability of the packaging and therefore a sterility of the product. If this is not a subject of the assessed MD, go to section 17.*** | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Shelf life / expiration date | | | | | | | | | | | | Comment of the manufacturer | | | | | | | | | | | | |
| 1. Specify the number of sterilization cycles that the product and its packaging were exposed to before stability testing | | | | | | | | | | | | Comment of the manufacturer | | | | | | | | | | | | |
| 1. Describe the used preconditioning (e.g. aging, transport, cleaning, disinfection, etc.): | | | | | | | | | | | | Comment of the manufacturer | | | | | | | | | | | | |
| 1. Has a compliance with requirements of EN ISO 11607 been proven? | | | | | | | | | | | | Yes | | | | | | | | No | | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. If the data obtained from the accelerated aging study were used to prove a shelf life of the product, specify the expected dates of start and end of the real-time stability study and submit the appropriate stability plan. | | | | | | | | | | | | | | | | | | | | | | | | |
| Start: Click here and enter the date. | | | | | | | | | | | | | End: Click here and enter the date. | | | | | | | | | | | |
| 1. Provide the title and number of the document(s) (reports) that evidence a shelf life of the product and the packaging. | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
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| NB 1023 review  The submitted data relating to the validation of packaging meet the requirements of EN ISO 11607-1/-2  Results of the accelerated stability study of the product  Plan of stability testing of the product and its packaging in real time  Adequate justification of selected attributes that will be tested in scope of proving the stability  Applied standards  Results of testing of the product in a scope of real stability study - protocols | | | | | | | | | | | | | | | | | | | | | | | | |
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| **NB 1023 review** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comments of assessor of the technical documentation | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the internal clinic (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of another assessor (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Finding | | | Yes | | | | | | | No | | | | | | | | Number of finding: Enter the number of finding | | | | | | |
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| Preclinical Evaluation | | | | | | | | | | | | | | | | | | | | | | | | |
| Biocompatibility | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is the product in a direct contact with the patient? **If No, proceed to section No. 17.2** | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| 1. Has a compliance with requirements of EN ISO 10993-1 been proven? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If No, please justify: | | | | | | | | | | | | | |  | | | | | | |  | | | |
| Comment of the manufacturer | | | | | | | | | | | | | |  | | | | | | |  | | | |
| 1. Categorization of the medical device according to the nature of contact with the human body: | | | | | | | | | | | | | | | | | | | | | | | | |
| skin | | | | | | | bloodstream, indirectly | | | | | | | | | | tissue / bone | | | | | | | |
| mucous membranes | | | | | | | tissue / bone / dentin | | | | | | | | | | blood | | | | | | | |
| damaged or weakened surfaces | | | | | | | circulating blood | | | | | | | | | |  | | | | | | | |
| 1. Categorization of the medical device according to the length of contact with the human body: | | | | | | | | | | | | | | | | | | | | | | | | |
| limited (≤ 24 h) | | | | | | | extended (> 24 h to 30 days) | | | | | | | | | | permanent (> 30 days) | | | | | | | |
| 1. Testing | | | | | | | | | | | | | | | | | | | | | | | | |
| * 1. Cytotoxicity according to EN ISO 10993-5, version Comment of the manufacturer | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please specify | | | | | | | | | | | | | | | | | | | | | | | | |
| * Institute that conducted the testing: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * Number of the protocol: Comment of the manufacturer, of the day of Click here and enter the date. | | | | | | | | | | | | | | | | | | | | | | | | |
| * Conclusion: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * 1. Skin sensitisations according to ISO 10993-10, version Comment of the manufacturer | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please specify | | | | | | | | | | | | | | | | | | | | | | | | |
| * Institute that conducted the testing: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * Number of the protocol: Comment of the manufacturer, of the day of Click here and enter the date. | | | | | | | | | | | | | | | | | | | | | | | | |
| * Conclusion: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * 1. Irritation (including intracutaneous reactivity) according to ISO 10993-10, version Comment of the manufacturer | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please specify | | | | | | | | | | | | | | | | | | | | | | | | |
| * Institute that conducted the testing: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * Number of the protocol: Comment of the manufacturer, of the day of Click here and enter the date. | | | | | | | | | | | | | | | | | | | | | | | | |
| * Conclusion: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * 1. Systemic toxicity (acute) and pyrogenicity according to ISO 10993-11, version Comment of the manufacturer | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please specify | | | | | | | | | | | | | | | | | | | | | | | | |
| * Institute that conducted the testing: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * Number of the protocol: Comment of the manufacturer, of the day of Click here and enter the date. | | | | | | | | | | | | | | | | | | | | | | | | |
| * Conclusion: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * 1. Subacute and sub-chronic toxicity according to EN ISO 10993-11, version Comment of the manufacturer | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please specify | | | | | | | | | | | | | | | | | | | | | | | | |
| * Institute that conducted the testing: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * Number of the protocol: Comment of the manufacturer, of the day of Click here and enter the date. | | | | | | | | | | | | | | | | | | | | | | | | |
| * Conclusion: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * 1. Genotoxicity and mutagenicity according to EN ISO 10993-3, version Comment of the manufacturer | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please specify | | | | | | | | | | | | | | | | | | | | | | | | |
| * Institute that conducted the testing: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * Number of the protocol: Comment of the manufacturer, of the day of Click here and enter the date. | | | | | | | | | | | | | | | | | | | | | | | | |
| * Conclusion: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * 1. Implantation according to EN ISO 10993-6, version Comment of the manufacturer | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please specify | | | | | | | | | | | | | | | | | | | | | | | | |
| * Institute that conducted the testing: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * Number of the protocol: Comment of the manufacturer, of the day of Click here and enter the date. | | | | | | | | | | | | | | | | | | | | | | | | |
| * Conclusion: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * 1. Compatibility with blood according to EN ISO 10993-4, version Comment of the manufacturer | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please specify | | | | | | | | | | | | | | | | | | | | | | | | |
| * Institute that conducted the testing: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * Number of the protocol: Comment of the manufacturer, of the day of Click here and enter the date. | | | | | | | | | | | | | | | | | | | | | | | | |
| * Conclusion: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * 1. Chronic toxicity according to EN ISO 10993-11, version Comment of the manufacturer | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please specify | | | | | | | | | | | | | | | | | | | | | | | | |
| * Institute that conducted the testing: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * Number of the protocol: Comment of the manufacturer, of the day of Click here and enter the date. | | | | | | | | | | | | | | | | | | | | | | | | |
| * Conclusion: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * 1. Carcinogenicity according to EN ISO 10993-3, version Comment of the manufacturer | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please specify | | | | | | | | | | | | | | | | | | | | | | | | |
| * Institute that conducted the testing: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * Number of the protocol: Comment of the manufacturer, of the day of Click here and enter the date. | | | | | | | | | | | | | | | | | | | | | | | | |
| * Conclusion: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * 1. Reproduction and developmental toxicity according to EN ISO 10993-3, version Comment of the manufacturer | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please specify | | | | | | | | | | | | | | | | | | | | | | | | |
| * Institute that conducted the testing: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * Number of the protocol: Comment of the manufacturer, of the day of Click here and enter the date. | | | | | | | | | | | | | | | | | | | | | | | | |
| * Conclusion: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * 1. Biodegradability according to EN ISO 10993-9, version Comment of the manufacturer | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please specify | | | | | | | | | | | | | | | | | | | | | | | | |
| * Institute that conducted the testing: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * Number of the protocol: Comment of the manufacturer, of the day of Click here and enter the date. | | | | | | | | | | | | | | | | | | | | | | | | |
| * Conclusion: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * 1. Toxicokinetics according to EN ISO 10993-16, version Comment of the manufacturer | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please specify | | | | | | | | | | | | | | | | | | | | | | | | |
| * Institute that conducted the testing: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * Number of the protocol: Comment of the manufacturer, of the day of Click here and enter the date. | | | | | | | | | | | | | | | | | | | | | | | | |
| * Conclusion: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * 1. Immunotoxicology according to ISO 10993-20, version Comment of the manufacturer | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please specify | | | | | | | | | | | | | | | | | | | | | | | | |
| * Institute that conducted the testing: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * Number of the protocol: Comment of the manufacturer, of the day of Click here and enter the date. | | | | | | | | | | | | | | | | | | | | | | | | |
| * Conclusion: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| * 1. Other tests | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please specify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| ***Note: The testing should be done on a final product or material. If a sterilization process forms a part of the manufacturing process, it is necessary to consider this fact and test a sterile product or material.*** | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Please justify the selection of tests: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Name and qualification of the person(s) who justified the selection of relevant tests. | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Provide the title and the number of the final report, summarizing the results of biocompatibility testing. | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Have the methods other than testing according to ISO 10993 standards been used to prove the biocompatibility? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please provide a name and number of the document that contains a qualified justification for not performing the relevant tests. | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Have the superseded (invalid) standards been used to prove the biocompatibility? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please provide a name and number of the document that contains a qualified justification (GAP analysis). | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Proving of qualification of testing laboratory. Please provide a title and a number of the document. | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | |  | | | | | | |  | | | | | | | |  | | | | | | |
| NB 1023 review  Application of EN ISO 10993-1 standard  Results of submitted tests and an acceptability of them  Justification of a selection of tests and their correctness with respect to the intended purpose of the MD  Competence and qualification of the person who justified the selection of tests | | | | | | | | | | | | | | | | | | | | | | | | |
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| **NB 1023 review** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of assessor of the technical documentation | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the internal clinic (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of another assessor (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Finding | | | Yes | | | | | | | No | | | | | | | | Number of finding: Enter the number of finding | | | | | | |
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| Medical Electrical Devices and Systems | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is a medical electrical instrument, system or software concerned? If No, please proceed to section 17.3. | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| ***If a medical electrical instrument, system or software is concerned, the following questions shall be answered and any relevant test reports provided. In case of software, it is also necessary to submit a design, validation and review of risks of the SW in accordance with the requirements of standard EN 62304.*** | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Are there applied the relevant requirements of current version of the standard EN 60601-1, including mandatory risk assessment according to EN ISO 14971? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If No, does the related standard (EN 60601-2-xx) follow the previous version of the standard EN 60601-1? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If a previous version of the standard EN 60601-1 has been used, please specify all applicable following standards of the EN 60601-2-xx family in table 2. | | | | | | | | | | | | | | | | | | | | | | | | |
| If a current version of the standard EN60601-1 has not been applied, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Please specify the names and numbers of the documents that prove a compliance with requirements of a version of the standard EN 60601-1, applied by yourself. | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. What is the estimated service life / usability of the instrument? | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is a necessary functionality of the device declared? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please describe: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Does software / firmware form a part of the instrument, or a standalone software according to MEDDEV 2.1/6 is concerned? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| Yes, does the submitted software documentation demonstrate a compliance with the requirements of EN 62304, including the risk assessment according to EN ISO 14971? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| Version of the applied standard EN 62304: Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| If the latest version of the standard has not been used, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Classification of SW: | | | | | | A | | | | | | | B | | | | | | | | C | | | |
| Justify a classification of the SW: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. To prove a compliance with the requirements of EN 62304, it is necessary to submit a documentation according to the table below. Please specify the name and number of the relevant document (report). | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| Table 1 - Requirements of the standard EN 62304 | | | | | | | | | | | | | | | | | | | | | | | | |
| Requirement | | | | | | | | Class A | | | | | | | Class B | | | | | | Class C | | | |
| 4.3 Software security classification | | | | | | | | X | | | | | | | X | | | | | | X | | | |
| 5.1 Software development planning | | | | | | | | X | | | | | | | X | | | | | | X | | | |
| 5.2 Software requirements analysis | | | | | | | | X | | | | | | | X | | | | | | X | | | |
| 5.3 Design of the SW architecture | | | | | | | | N/A | | | | | | | X | | | | | | X | | | |
| 5.4 Detailed design of the SW | | | | | | | | N/A | | | | | | | X | | | | | | X | | | |
| 5.5 Implementation of SW units and their verification | | | | | | | | X | | | | | | | X | | | | | | X | | | |
| 5.6 Integration of SW and integration tests | | | | | | | | N/A | | | | | | | X | | | | | | X | | | |
| 5.7 SW system tests | | | | | | | | N/A | | | | | | | X | | | | | | X | | | |
| 5.8 Release of the SW | | | | | | | | X | | | | | | | X | | | | | | X | | | |
| 6.1 Setting of the SW maintenance plan | | | | | | | | X | | | | | | | X | | | | | | X | | | |
| 6.2 Analysis of problems and modifications | | | | | | | | X | | | | | | | X | | | | | | X | | | |
| 6.3 Implementation of modifications | | | | | | | | X | | | | | | | X | | | | | | X | | | |
| 7.1 Analysis of possible states of the SW that may lead to hazardous situations | | | | | | | | N/A | | | | | | | X | | | | | | X | | | |
| 7.2 Risk management measures | | | | | | | | N/A | | | | | | | X | | | | | | X | | | |
| 7.3 Evaluation of accepted risk management measures | | | | | | | | N/A | | | | | | | X | | | | | | X | | | |
| 7.4 Risk management at modification of the SW | | | | | | | | X | | | | | | | X | | | | | | X | | | |
| 8 System configuration management process | | | | | | | | X | | | | | | | X | | | | | | X | | | |
| 9 SW problem solving process | | | | | | | | X | | | | | | | X | | | | | | X | | | |
|  | | | | | | | |  | | | | | | |  | | | | | |  | | | |
| Group standards | | | | | | | | | | | | | | | | | | | | | | | | |
| EN 60601-1-X | | Year | | | Name | | | | | | | | | | | | | | | | Applied / Report | | | |
| EN 60601-1-2 | | Comment of the manufacturer | | | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests | | | | | | | | | | | | | | | | Yes | | | No |
|  | |  | | |  | | | | | | | | | | | | | | | | Report: Comment of the manufacturer | | | |
| EN 60601-1-3 | | Comment of the manufacturer | | | Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment | | | | | | | | | | | | | | | | Yes | | | No |
|  | |  | | |  | | | | | | | | | | | | | | | | Report: Comment of the manufacturer | | | |
| EN 60601-1-6 | | Comment of the manufacturer | | | Medical electrical equipment - Part 1- 6: General requirements for basic safety and essential performance - Collateral standard: Usability | | | | | | | | | | | | | | | | Yes | | | No |
|  | |  | | |  | | | | | | | | | | | | | | | | Report: Comment of the manufacturer | | | |
| EN 60601-1-8 | | Comment of the manufacturer | | | Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems | | | | | | | | | | | | | | | | Yes | | | No |
|  | |  | | |  | | | | | | | | | | | | | | | | Report: Comment of the manufacturer | | | |
| EN 60601-1-10 | | Comment of the manufacturer | | | Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers | | | | | | | | | | | | | | | | Yes | | | No |
|  | |  | | |  | | | | | | | | | | | | | | | | Report: Comment of the manufacturer | | | |
| EN 60601-1-11 | | Comment of the manufacturer | | | Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment | | | | | | | | | | | | | | | | Yes | | | No |
|  | |  | | |  | | | | | | | | | | | | | | | | Report: Comment of the manufacturer | | | |
| Please justify why the above group standards have not been applied: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | |
| Table No.2 – Standards containing special requirements | | | | | | | | | | | | | | | | | | | | | | | | |
| |  |  |  |  | | --- | --- | --- | --- | | **EN 60601-2-X\*** | **Year** | **Name** | **Report No.** | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer |   ***Add additional rows if necessary (place the cursor on an end of the table row and Enter).*** | | | | | | | | | | | | | | | | | | | | | | | | |
| ***\*Please specify also standards of 80601-2-X family if they are applicable.*** | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | |
| Table No.3 – Other applied standards | | | | | | | | | | | | | | | | | | | | | | | | |
| ***The manufacturer is obliged to consider using of other standards that are related to an active MD, as are e.g. EN 62366, EN 60645, EN 60627, EN 60522, etc.*** | | | | | | | | | | | | | | | | | | | | | | | | |
| |  |  |  |  | | --- | --- | --- | --- | | **EN 60601-2-X\*** | **Year** | **Name** | **Report No.** | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer. | Comment of the manufacturer | | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer | Comment of the manufacturer |   ***Add additional rows if necessary (place the cursor on an end of the table row and Enter).*** | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Proving of qualification of the testing laboratory. Provide the title and number of the document. | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | |  | | | | | | |  | | | | | | | |  | | | | | | |
| NB 1023 review  Compliance with requirements of standard EN ISO 60601-1  Results of the submitted tests and their acceptability  Compliance with requirements of standard EN 62304  Application of all relevant collateral (group) standards  Application of all relevant standards containing special requirements | | | | | | | | | | | | | | | | | | | | | | | | |
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| **NB 1023 review** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of assessor of the technical documentation | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the internal clinic (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of another assessor (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Finding | | | Yes | | | | | | | No | | | | | | | | Number of finding: Enter the number of finding | | | | | | |
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| Testing of Functional Suitability (Performance) and Tests of Simulated Use | | | | | | | | | | | | | | | | | | | | | | | | |
| ***For Class IIb implantable and Class III products it is necessary to provide the design and development documentation for the product, which must include:***   * ***Inputs for design and development / product requirements*** * ***Specifications for each input and used source (harmonized / non-harmonized standards, ASTM, AAMI, internal specifications, etc.)*** * ***Outputs from design and development / documents and records leading to proving of compliance with requirements of design and development*** * ***Comment of the manufacturer on whether the input requirements for design and development have been met*** | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Please submit all relevant tests, related to design verification that confirm a fulfilment of the design and development input requirements. | | | | | | | | | | | | | | | | | | | | | | | | |
| |  |  |  |  | | --- | --- | --- | --- | | Input for design and development | Harmonized standard / Non-harmonized standard or other procedure / specification | Justification of using to meet the MDD requirements | Output from Design and Development (references to relevant documents) | | Tests of fatigue properties | ISO12189 | Requirements relating to the design of the MD, Annex I to MDD, point 9.2 | TCF-01\_225 | | Measurement of thickness of plating | ASTM F1854 | Requirements relating to the physical properties of the MD, Annex I to MDD, point 9.2 | TCF-03\_225 | |  |  |  |  | |  |  |  |  |   ***Add additional rows if necessary (place the cursor on an end of the table row and Enter).*** | | | | | | | | | | | | | | | | | | | | | | | | |
| ***Fill in the table according to the prescribed pattern. Using of non-harmonized standards or other specifications shall be duly substantiated. If necessary, add rows to specify any documented test protocols.*** | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Do the submitted reports / test protocols contain the following information? | | | | | | | | | | | | | | | | | | | | | | | | |
| Selected test parameters according to the applied standards | | | | | | | | | | | | | | | | | | | | | | | | |
| Justification of selection of a sample | | | | | | | | | | | | | | | | | | | | | | | | |
| Acceptance criteria | | | | | | | | | | | | | | | | | | | | | | | | |
| Justification of deviations (if relevant) | | | | | | | | | | | | | | | | | | | | | | | | |
| If any of the above points is not met, please justify. | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | |  | | | | | | |  | | | | | | | |  | | | | | | |
| NB 1023 review  Inputs for design and development  Outputs from design and development proving a compliance with product requirements  Testing of a functional suitability of the product  Tests of simulated use | | | | | | | | | | | | | | | | | | | | | | | | |
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| **NB 1023 review** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of assessor of the technical documentation | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the internal clinic (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of another assessor (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Finding | | | Yes | | | | | | | No | | | | | | | | Number of finding: Enter the number of finding | | | | | | |
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| Animal Testing | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Have there been performed the in vivo animal studies that confirm safety and/or efficacy of the design? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If No, **proceed to section 18.** | | | | | | | | | | | | | | | | | | | | | | | | |
| If the animal tests have been performed, please provide the name and number of the document(s): | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Do the submitted data contain detailed information on the performed tests on animals and animal models? | | | | | | | | | | | | | | | | | | | | | | | | |
| Objectives of the study | | | | | | | | | | | | | | | | | | | | | | | | |
| Methodology | | | | | | | | | | | | | | | | | | | | | | | | |
| Justification for selection of the model(s) | | | | | | | | | | | | | | | | | | | | | | | | |
| Results, analyses and conclusions | | | | | | | | | | | | | | | | | | | | | | | | |
| If any of the above points is not fulfilled, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Have the animal studies of an equivalent product been used? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | |  | | | | | | |  | | | | | | | |  | | | | | | |
| NB 1023 review  Justification for selection of the tests  Completeness of provided tests and compliance with applicable standards and specifications  Animal testing of an equivalent product and demonstration of equivalence | | | | | | | | | | | | | | | | | | | | | | | | |
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| **NB 1023 review** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of assessor of the technical documentation | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the internal clinic (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of another assessor (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Finding | | | Yes | | | | | | | No | | | | | | | | Number of finding: Enter the number of finding | | | | | | |
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| Clinical Evaluation | | | | | | | | | | | | | | | | | | | | | | | | |
| Plan of Clinical Evaluation | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is a part of submitted documentation the plan of clinical evaluation? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please provide the name and number of the document. | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer. | | | | | | | | | | | | | | | | | | | | | | | | |
| If a separate document is not submitted, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer. | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is the process of clinical evaluation set in accordance with MEDDEV 2.7/1 rev. 4? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer. | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Have other methodologies been used in the clinical evaluation? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer. | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. In case the manufacturer comes from outside EU, EEA, Switzerland and Turkey, please provide national regulations governing the sphere of medical devices and the applied provisions. | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer. | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | |  | | | | | | |  | | | | | | | |  | | | | | | |
| NB 1023 review  Plan of clinical evaluation  Compliance with requirements of MEDDEV 2.7/1 rev. 4  Other national regulations, if relevant | | | | | | | | | | | | | | | | | | | | | | | | |
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| **NB 1023 review** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comments of internal clinician | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comments of clinical expert (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Finding | | | Yes | | | | | | | No | | | | | | | | Number of finding: Enter the number of finding | | | | | | |
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| Identification of Authors of Clinical Evaluation | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Please provide full names and titles of the authors of the clinical evaluation. | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer. | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Are there provided the professional CVs of all persons performing the clinical evaluation? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer. | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Are there presented their statements of conflict of interest? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer. | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Justification for selection of evaluators. | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer. | | | | | | | | | | | | | | | | | | | | | | | | |
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| NB 1023 review  CVs of persons involved in preparation of CE  Selection of evaluators  Exclusion of conflict of interest of persons involved in the preparation of CE | | | | | | | | | | | | | | | | | | | | | | | | |
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| **NB 1023 review** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comments of internal clinician | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comments of clinical expert (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Finding | | | Yes | | | | | | | No | | | | | | | | Number of finding: Enter the number of finding | | | | | | |
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| Clinical Evaluation Report - CER | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is a part of submitted documentation the clinical evaluation report? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please provide the name and number of the document: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| If the CER does not contain a marking of version and a list of revisions and changes, it is necessary to submit all CERs linked to each other. If these are not submitted, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer. | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. How often is the CER updated? | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Justification of set frequency of updating. | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | |  | | | | | | |  | | | | | | | |  | | | | | | |
| NB 1023 review  Final report of clinical evaluation  Updating of CER and justification of set interval | | | | | | | | | | | | | | | | | | | | | | | | |
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| **NB 1023 review** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comments of internal clinician | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comments of clinical expert (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Finding | | | Yes | | | | | | | No | | | | | | | | Number of finding: Enter the number of finding | | | | | | |
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| Documentation on Collection of Clinical Data | | | | | | | | | | | | | | | | | | | | | | | | |
| Documentation on Pre-Marketing Clinical Trial (eventually on clinical trial in purpose to extend the intended purpose) | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is a part of submitted documentation the plan (protocol) of clinical trial? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please provide the name and number of the document: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is a part of submitted documentation the Consent Opinion of the Ethic Committee, in the case of a multicentric clinical trial, the opinions of all ethics committees? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please provide the name and number of the document: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is a part of submitted documentation the consent opinion of the competent authority, in case of international clinical trials the opinions of the competent authorities (or other regulatory authorities) of all countries where the clinical trial is performed? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please provide the name and number of the document: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Has the clinical trial been performed in accordance with harmonized technical standard EN ISO 14155? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please provide the name and number of the document: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is a part of submitted documentation the final report of the clinical trial? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please provide the name and number of the document: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. If the clinical trial has not been performed, is a part of submitted documentation the justification for not performing the clinical trial? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please provide the name and number of the document: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
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| NB 1023 review  Plan of the clinical trial  Opinion of the ethic committee, if relevant  Compliance with requirements of standard EN ISO 14155  Justification for not performing the clinical trial, if relevant | | | | | | | | | | | | | | | | | | | | | | | | |
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| **NB 1023 review** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comments of internal clinician | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comments of clinical expert (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Finding | | | Yes | | | | | | | No | | | | | | | | Number of finding: Enter the number of finding | | | | | | |
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| Documentation of Literary Research | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is a part of submitted documentation the plan (protocol) of literary research? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please provide the name and number of the document: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is a part of submitted documentation a report of literary research? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please provide the name and number of the document: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Are there submitted the full wordings of all publications that were used as a source for relevant clinical data? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Justification of collection of clinical data in a form of literary research. | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
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| NB 1023 review  Plan / protocol of literary research  Report of literary research  Sources of clinical data, including justification of their selection | | | | | | | | | | | | | | | | | | | | | | | | |
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| **NB 1023 review** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comments of internal clinician | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comments of clinical expert (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Finding | | | Yes | | | | | | | No | | | | | | | | Number of finding: Enter the number of finding | | | | | | |
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| Documentation To Prove an Equivalence of the Medical Device | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is a part of submitted documentation the evaluation of equivalence with a different medical device? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If No, **proceed to section 18.4.4** | | | | | | | | | | | | | | | | | | | | | | | | |
| If Yes, please provide the name and number of the document: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Identification of a chosen equivalent device (provide a full trade name and a registered name of a manufacturer) | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Have there been submitted the documents that can be considered an objective source of information on an equivalent medical device and a document proving compliance with the requirements of Directive 93/43/EEC? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please provide the name and number of the document: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
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| NB 1023 review  Proving of biological, technical and clinical equivalence  Identification of equivalent medical devices  Equivalent medical devices meet the requirements of Directive 93/42/EEC | | | | | | | | | | | | | | | | | | | | | | | | |
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| **NB 1023 review** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comments of internal clinician | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comments of clinical expert (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Finding | | | Yes | | | | | | | No | | | | | | | | Number of finding: Enter the number of finding | | | | | | |
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| Post-Marketing Clinical Follow-up Surveillance (PMCF) | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is a part of submitted documentation the PMCF plan? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| 1. Does the PMCF plan contain a set-up of collection of clinical data according to MEDDEV 2.12/2 rev. 2? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If yes, continue below, if not, please justify and write down the method of collection of clinical data within the scope of PMCF and identify the relevant documents. | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| ***Post-marketing clinical study:*** | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is a part of submitted documentation the plan of post-marketing clinical study? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please provide the name and number of the document: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is a part of submitted documentation the report of post-marketing clinical study? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please provide the name and number of the document: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is a part of submitted documentation the consent opinion of ethical committee? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please provide the name and number of the document: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| ***Register of medical devices (managed by the manufacturer):*** | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is a part of submitted documentation the plan (targets) of the register of medical devices? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please provide the name and number of the document: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is a part of submitted documentation the evaluation of data from the register of medical devices / summary report? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please provide the name and number of the document: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| ***Case studies:*** | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is a part of submitted documentation the plan (targets) of collection of clinical data by means of case studies? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please provide the name and number of the document: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is a part of submitted documentation the evaluation of case studies / summary report? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please provide the name and number of the document: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| ***Individual opinions of physicians / questionnaire survey focused on collecting of clinical data:*** | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is a part of submitted documentation the plan and the form with questions for collection of clinical data? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please provide the name and number of the document: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Is a part of submitted documentation the evaluation of questionnaire survey / summary report? | | | | | | | | | | | | | | Yes | | | | | | | No | | | |
| If Yes, please provide the name and number of the document: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| If No, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
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| NB 1023 review  PMCF plan  Post-marketing clinical studies  Data from register of medical devices  Case studies and forms for collection of clinical data | | | | | | | | | | | | | | | | | | | | | | | | |
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| **NB 1023 review** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comments of internal clinician | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comments of clinical expert (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Finding | | | Yes | | | | | | | No | | | | | | | | Number of finding: Enter the number of finding | | | | | | |
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| Post-Marketing Surveillance | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Procedure for a surveillance of the product after a placement of it on the its market. Provide the title and number of the document. | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Procedure for solving of adverse events and recalls of the product from market (vigilance). Provide the title and number of the document. | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
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| NB 1023 review  PMS procedure  Procedure for vigilance, including procedure for recall of the product from market and issue of a safety notice  Compliance of a procedure for vigilance with requirements of MEDDEV 2.12-1 | | | | | | | | | | | | | | | | | | | | | | | | |
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| **NB 1023 review** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of assessor of the technical documentation | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the internal clinic (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of another assessor (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Finding | | | Yes | | | | | | | No | | | | | | | | Number of finding: Enter the number of finding | | | | | | |
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| Declaration of Conformity | | | | | | | | | | | | | | | | | | | | | | | | |
| ***Draft of the Declaration of Conformity relates to the products and their variants listed in this application and not to other products.*** | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. The submitted draft of document of the Declaration of Conformity contains the following information: | | | | | | | | | | | | | | | | | | | | | | | | |
| Number of document  Subject of the declaration including product name, trade names, models and variants of the product  Classification class and applied classification rule  Selected procedure for conformity assessment (applied Annex to the MDD Directive)  Name of the manufacturer, residence address, production address (if different)  Name and address of the authorized EU representative (if relevant)  Declaration that the concerned product meets the requirements of MDD  References to applied harmonized and non-harmonized standards (including a name of the standard and the date of issue of the applied revision of the standard)  Identification of the Notified Body that had performed the conformity assessment (number, name and address) | | | | | | | | | | | | | | | | | | | | | | | | |
| If any of the above points is not fulfilled, please justify: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
| Provide the title and number of the document: | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the manufacturer | | | | | | | | | | | | | | | | | | | | | | | | |
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| NB 1023 review  Draft of Declaration of Conformity | | | | | | | | | | | | | | | | | | | | | | | | |
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| **NB 1023 review** | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of assessor of the technical documentation | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of the internal clinic (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Comment of another assessor (if required) | | | | | | | | | | | | | | | | | | of the day of Click here and enter the date. | | | | | | |
| Comment of NB1023 | | | | | | | | | | | | | | | | | | | | | | | | |
| Finding | | | Yes | | | | | | | No | | | | | | | | Number of finding: Enter the number of finding | | | | | | |
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| Conclusions of the Review | | | | | | | | | | | | | | | | | | | | | | | | |
| Finding No.*NB 1023 number of finding*; classification of the finding: **Select a classification**  Description of the finding (shall be filled in by NB 1023) insert a text  Response towards the finding by manufacturer insert a text  Response towards the corrective action to the finding by NB 1023 insert a text | | | | | | | | | | | | | | | | | | | | | | | | |

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| Annex No. 1 (Medical Devices with a Content of Drug Substances) | | | | | |
| 1. If a part of the medical device is a drug substance, please provide a documentation file with detailed description of the drug substance, processed in accordance with regulation MEDDEV 2.1.3, section B3 (A-Q). | | | | | |
| Name of the drug substance | | Comment of the manufacturer | | | |
| Name and address of manufacturer of the drug substance | | Comment of the manufacturer | | | |
| Name and address of supplier of the drug substance | | Comment of the manufacturer | | | |
| Function of the drug substance in the medical device | | Comment of the manufacturer | | | |
| EDQM certificate for the drug substance (Yes / No) | | Comment of the manufacturer | | | |
| *(Note - a validity of the NB 1023 Certificate shall not exceed the validity of the EDQM Certificate)* | | | | | |
| ***If you do not have available an EDQM certificate, please submitt the Drug Master File of the drug substance.*** | | | | | |
| Provide the title and number of the document. | | | | | |
| Comment of the manufacturer | | | | | |
|  |  | | |  |  |
| NB 1023 review  Has the documentation file been supplied complete and in accordance with the requirements of the guideline MEDDEV 2.1.3 Sekce B3 (A-Q)?  If the EDQM certificate has been provided, is it valid for the relevant drug substance? | | | | | |
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| **NB 1023 review** | | | | | |
| Comment of assessor of the technical documentation | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the internal clinic (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the pharmacist (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Finding | Yes | | | No | Number of finding: Enter the number of finding |
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|  | | | | | |
| 1. Qualitative and Quantitative Data on Ingredients | | | | | |
| ***Please provide the composition and quantity (or state the upper and lower limits of the quantity) of the drug substance contained in each medical device. If the drug substance is being modified upon placing into a medical device, please provide relevant information:*** | | | | | |
| Comment of the manufacturer | | | | | |
|  |  | | |  |  |
| NB 1023 review  Are the submitted data sufficient? | | | | | |
|  | | |  | | |
| **NB 1023 review** | | | | | |
| Comment of assessor of the technical documentation | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the internal clinic (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the pharmacist (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Finding | Yes | | | No | Number of finding: Enter the number of finding |
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| 1. Description of the Manufacturing Procedure | | | | | |
| ***To supplement the provided overall description, please provide details on inclusion of the drug substance in each medical device. If the drug substance is modified in any way prior incorporating into the medical device, please provide the relevant information:*** | | | | | |
| Comment of the manufacturer | | | | | |
|  |  | | |  |  |
| NB 1023 review  Are the submitted data sufficient? | | | | | |
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| **NB 1023 review** | | | | | |
| Comment of assessor of the technical documentation | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the internal clinic (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the pharmacist (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Finding | Yes | | | No | Number of finding: Enter the number of finding |
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| 1. Inspection of Input Materials | | | | | |
| ***Provide a specification of the drug substance. If possible, refer to the European Pharmacopoeia (EP) or, if no monograph of the drug substance exists in the EP, to a monograph of the drug substance in a national pharmacopoeia of any of the EU Member States. If there is no monograph of the drug substance in the pharmacopoeia of any of the Member States, reference may be made to other national monographs or to the manufacturer's specifications and analytical methods.***  ***In case of new drug substances and some known substances, additional information will be required, which may be provided in a form of a Drug Master File. We recommend to use a guideline "Requirements related to drug substances" directive, which lists the cases in which it may be necessary to add a reference to the pharmacopoeial monograph for further information:*** | | | | | |
| Comment of the manufacturer | | | | | |
|  |  | | |  |  |
| NB 1023 review  Does the specification of the drug substance contain a reference to the European Pharmacopoeia?  If not, is there provided a reference to the national pharmacopoeia of one of the EU Member States?  If not, what has been used?  Is the Drug Master File required and provided? | | | | | |
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| **NB 1023 review** | | | | | |
| Comment of assessor of the technical documentation | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the internal clinic (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the pharmacist (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Finding | Yes | | | No | Number of finding: Enter the number of finding |
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| 1. Inspection of Tests Carried Out in Stages of Individual Intermediates in the Manufacturing Process of the Medical Device | | | | | |
| ***If needed, it is necessary to provide information concerning the inspection of the tests carried out in stages of the individual intermediates of the manufacturing process.*** | | | | | |
| Comment of the manufacturer | | | | | |
|  |  | | |  |  |
| NB 1023 review  **This information is only necessary if it relates directly to a quality of the substance forms a part of the medical device.** | | | | | |
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| **NB 1023 review** | | | | | |
| Comment of assessor of the technical documentation | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the internal clinic (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the pharmacist (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Finding | Yes | | | No | Number of finding: Enter the number of finding |
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|  |  | | |  |  |
| 1. Inspection of Tests of the Final Product | | | | | |
| ***Please specify the details of qualitative and quantitative tests performed during control of the drug substance in the medical device.*** | | | | | |
| Comment of the manufacturer | | | | | |
|  |  | | |  |  |
| NB 1023 review  Are introduced the appropriate controls? | | | | | |
|  | | |  | | |
| **NB 1023 review** | | | | | |
| Comment of assessor of the technical documentation | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the internal clinic (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the pharmacist (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Finding | Yes | | | No | Number of finding: Enter the number of finding |
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| 1. Toxicity | | | | | |
| ***Please provide a reference to a known toxicological profile of the drug substance. In case of new drug substances, it is needed to provide results of the toxicity test.*** | | | | | |
| Comment of the manufacturer | | | | | |
|  |  | | |  |  |
| NB 1023 review  **Assess the provided toxicological profile. The assessment may include information on toxicity and biocompatibility of the medical device that may be available on basis of evaluation of results according to standards EN ISO 10993.** | | | | | |
|  | | |  | | |
| **NB 1023 review** | | | | | |
| Comment of assessor of the technical documentation | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the internal clinic (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the pharmacist (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Finding | Yes | | | No | Number of finding: Enter the number of finding |
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| 1. Reproduction Function | | | | | |
| ***Provide a reference to the known profile of the drug substance concerning its effect on reproductive function. In case of new drug substances, it is needed to provide results of the relevant tests.*** | | | | | |
| Comment of the manufacturer | | | | | |
|  |  | | |  |  |
| NB 1023 review  **Assess the provided profile, similar conditions as in case of toxicity apply.** | | | | | |
|  | | |  | | |
| **NB 1023 review** | | | | | |
| Comment of assessor of the technical documentation | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the internal clinic (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the pharmacist (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Finding | Yes | | | No | Number of finding: Enter the number of finding |
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| 1. Embryonal / Foetal and Perinatal Toxicity | | | | | |
| ***Provide a reference to the known embryonal / foetal and perinatal toxicological profile of the drug substance. In case of new drug substances, it is needed to provide results of the toxicity test.*** | | | | | |
| Comment of the manufacturer | | | | | |
|  |  | | |  |  |
| NB 1023 review  **Assess the provided profile, similar conditions as in case of toxicity apply.** | | | | | |
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| **NB 1023 review** | | | | | |
| Comment of assessor of the technical documentation | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the internal clinic (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the pharmacist (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Finding | Yes | | | No | Number of finding: Enter the number of finding |
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| 1. Mutagenic potential | | | | | |
| ***Provide a reference to the known mutagenic potential of the drug substance. In case of new drug substances, it is needed to provide results of the relevant tests.*** | | | | | |
| Comment of the manufacturer | | | | | |
|  |  | | |  |  |
| NB 1023 review  **Assess the provided profile, similar conditions as in case of toxicity apply.** | | | | | |
|  | | |  | | |
| **NB 1023 review** | | | | | |
| Comment of assessor of the technical documentation | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the internal clinic (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the pharmacist (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Finding | Yes | | | No | Number of finding: Enter the number of finding |
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| 1. Carcinogenic Potential | | | | | |
| ***Provide information concerning the carcinogenic potential of the drug substance.*** | | | | | |
| Comment of the manufacturer | | | | | |
|  |  | | |  |  |
| NB 1023 review  **The scope of requested data on carcinogenicity of the drug substance shall be established taking into account the available information on the drug substance, the results of the genotoxicity tests, chemical structure of the drug substance and the duration of potential exposure of the drug substance.** | | | | | |
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| **NB 1023 review** | | | | | |
| Comment of assessor of the technical documentation | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the internal clinic (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the pharmacist (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Finding | Yes | | | No | Number of finding: Enter the number of finding |
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| 1. Pharmacodynamics | | | | | |
| ***Provide information on the intended effect of the drug substance concerning its inclusion into the medical device.*** | | | | | |
| Comment of the manufacturer | | | | | |
|  |  | | |  |  |
| NB 1023 review  **Review the provided information to make sure they sufficiently describe the intended effects of the drug substance in connection with its inclusion in the medical device.** | | | | | |
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| **NB 1023 review** | | | | | |
| Comment of assessor of the technical documentation | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the internal clinic (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the pharmacist (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Finding | Yes | | | No | Number of finding: Enter the number of finding |
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| 1. Pharmacokinetics | | | | | |
| ***Provide information on pharmacokinetics, concerning all applicable points below:*** | | | | | |
| * Description of a pattern of local and systemic exposure to the drug substance. * If the exposure level varies, the maximum exposure level and exposure time shall be considered. * If it is considered that the potential levels of systemic exposure may pose a safety risk, the maximum peak concentration of the drug substance in blood plasma shall be determined with a due concern to individual variability. * In case of new drug substances, the information on their release from the medical device shall be provided and if relevant, also on their subsequent distribution and elimination. | | | | | |
| Comment of the manufacturer | | | | | |
|  |  | | |  |  |
| NB 1023 review  Have the above mentioned items been adequately covered? | | | | | |
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| **NB 1023 review** | | | | | |
| Comment of assessor of the technical documentation | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the internal clinic (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the pharmacist (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Finding | Yes | | | No | Number of finding: Enter the number of finding |
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| 1. Local Tolerance | | | | | |
| ***Please provide information on local tolerance of the drug substance.*** | | | | | |
| Comment of the manufacturer | | | | | |
|  |  | | |  |  |
| NB 1023 review  **This point is very significant because the way of exposure of the drug substance may differ from that of its conventional application. It is necessary to present the results of relevant tests of the medical device according to the standards of the EN ISO 10993 series, eventually information from the professional literature.** | | | | | |
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| **NB 1023 review** | | | | | |
| Comment of assessor of the technical documentation | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the internal clinic (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the pharmacist (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Finding | Yes | | | No | Number of finding: Enter the number of finding |
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| 1. Risk Analysis – Additional | | | | | |
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| NB 1023 review  **Assess the provided risk analysis, especially make sure that it contains a critical safety assessment of the combination of the drug substance and the medical device.** | | | | | |
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| **NB 1023 review** | | | | | |
| Comment of assessor of the technical documentation | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the internal clinic (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the pharmacist (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Finding | Yes | | | No | Number of finding: Enter the number of finding |
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| 1. Stability – Additional | | | | | |
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| NB 1023 review  **Assess the submitted stability data, in particular make sure that the drug substance maintains its required function throughout a shelf life of the medical device, taking into account the recommended storage conditions of the manufacturer.** | | | | | |
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| **NB 1023 review** | | | | | |
| Comment of assessor of the technical documentation | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the internal clinic (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Comment of the pharmacist (if required) | | | | | of the day of Click here and enter the date. |
| Comment of NB1023 | | | | | |
| Finding | Yes | | | No | Number of finding: Enter the number of finding |
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| 1. Review of an Appropriate Authority (Opinion of the State Institute for Drug Control) | | | | | |
|  |  | | |  |  |
| NB 1023 review | | | | | |
| Details of opinion of the relevant regulatory authority: | | | | | |
| Comment of NB1023 | | | | | |
| Date of request for opinion: | | | | Date of receipt of opinion: | |
| Klikněte sem a zadejte datum | | | | Klikněte sem a zadejte datum | |
| Summary of the opinion of the regulatory authority: | | | | | |
| Comment of NB1023 | | | | | |