Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
tflda Tomáše Bati 299, Louky, 763 02 Zlln, Czech Republic

EC Certificate - Full Quality Assurance System

No. 17 0306 QS/NB

The quality system of manufacturer

SADIA UA LTD

Mykoly Borovskogo Street, 10 Odesa, Odes'ka oblast, Ukraine

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II.

for the following product category(ies):

ACCESSORY. SURGICAL(SINGE-USE MEDICAL FACE MASK. KN95, DISPOSABLE PROTECTIVE MASK)

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices/ device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class III devices covered by this certificate, an EC Design-Examination Certificate according to Annex II (Section 4) is required.

Valid from: 2020-01-25
Valid until: 2022-06-25
First Issued: 2018-06-30

Revision: a

Date: 2020-01-25

NOTIFIED BODY 1023 INSTITUTE FOR TESTING AND CERTIFICATION

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

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Mykoly Borovskogo Street, 10 Odesa, Odes'ka oblast, Ukraine

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II.

for the following product category(ies):

LATEX PATIENT EXAMINATION GLOVE & NITRILE PATIENT EXAMINATION GLOVE

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class III devices covered by this certificate, an EC Design-Examination Certificate according to Annex II (Section 4) is required.

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