



Notified Body
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlín, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 16 2282 QS/NB

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws) certifies that the products:-
medical device as blowing: Non woven medical/surgical facemask, sterile and nonsterile medical gown, medical isolation gown are in conformity with the provision of EU Regulations

See Annex II

Manufactured by company:

SPEZTEHPROM MED LLC (ТОВ СПЕЦТЕХПРОМ МЕД)
39600, UKRAINE, POLTAVA
KREMENCHUG, STR. KIEVSKA 3a

is manufactured under conditions fulfilling the quality system requirements of Annex V, Section 3.3., of the Directive 93/42/EEC as amended.

The Notified Body No. 1023 has performed an audit of the above products manufacturing quality system, concerning aspects aimed to conformity of these products with the metrological requirements. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex V, Section 3.3. and 5., of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803601986/2016, which is enclosed to this Certificate.

Condition of this Certificate use and related information:

1. It applies only to the quality system maintained in the manufacture of the above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.
2. The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the 27th February 2021 at the latest.
3. The Certificate validity is conditioned by positive results of surveillance audits.
4. After fulfilling the relevant EU legislation requirements, the manufacturer shall affix to each medical device, of the above referenced models, the CE marking followed by the number of the Notified Body according to this example:



Issued in Zlín, on 28th February 2019

RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023