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international

3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia
Notified Body No. 2265

EC CERTIFICATE

No. 2020-MDD/QS-024

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Slovak Government Decree No. 582/2008 Coll. as amended by 215/2013 Coll. certifies that the medical device of Class IIb,

Multifunctional Laser Device MULTILINE
With laser heads: Nd:YAP/Q-sw, Nd:YAP/Q-sw with KTP module, Nd:YAP, RUBY, ALEX, Er:YAG

manufactured by company

LINLINE Medical Systems Co. Ltd.
Antonovskaya Str. 28A, 220088 Minsk, Belarus

is manufactured under conditions fulfilling the quality system requirements of Annex II, excluding (4), of the Directive 93/42/EEC as amended.

The Notified Body No. 2265 has performed an audit of the above device quality system. The full quality assurance system has been assessed and found that it meets the requirements above. The quality system is subject to continuous surveillance according to Annex II, Sections 3.3, and 5, of the Directive 93/42/EEC as amended. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. 310369 and the Final protocol No. 310369/2020.

This certificate is issued under the following conditions:

It applies only to the quality system maintained in the manufacture of the above-referenced model of medical device and it does not substitute the design or type-examination procedures if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until May 26th, 2024 at the latest. The certificate ,validity is conditional upon positive results of regular surveillance audits and fulfilment of relevant legal and other requirements by the manufacturer.

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

Dr. Katarína Tomin Srdošová
Responsible to act on behalf of NB 2265

At Bratislava, on April 9th, 2020

LINLINE Medical Systems Co. Ltd.
Antonovskaya Str. 28A,
220088 Minsk,
Belarus

Our reference	***Contact person***	BRATISLAVA
LUL/2022/012	Ľubor Lysák / +421 2 5831 8343	April 08th, 2022

Subject: Confirmation of the announced change

To whom it may concern,

This is to confirm that 3EC International a.s. Notified body No. 2265 according to the Regulation (EU) 2017/745 as amended approves the announced establishment of the new manufacturing site (ref. F01Z from 16.12.2020) of the company based on the audit report No. 301 dt. 04.04.2022 as follows:

New manufacturing site:

LINLINE Medical Systems SIA, Krasta iela 105A, LV-1019 Riga, Latvia

Implementation of the change does not represent a significant change in design or intended purpose under Art. 120 sec.3 of the Regulation (EU) 2017/745 on medical devices as amended. The related EC certificates are listed in the Annex and remain valid until the date stated on the certificates. This confirmation corrects/complements the information on the above-mentioned certificate.

Yours sincerely

3EC International a.s.
Hraničná 18, 821 05 Bratislava
Slovak Republic
ID No.: 36 789 003
VAT No.: SK2022390073

3EC International a.s.
Ľubor Lysák
Deputy Director of NB2265 & In-house Counsel

Annex: List of affected EC certificates
2020-MDD/QS-024