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

EC CERTIFICATE

No. 2018-MDD/QS-023

issued in compliance with the Council Directive 93/42/EEC as amended by 2007/47/EC, 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 IIa,

Dental Units, Type: ARIA
Variants: ARIA EXCELL S, ARIA EXCELL SE, ARIA EXCELL SR, ARIA EXCELL TR, ARIA PRIMA S, ARIA PRIMA SE, ARIA PRIMA SR, ARIA PRIMA TR

manufactured by company

NEOMED, s.r.o.
Gaštanová 2, 066 01 Humenné, Slovak Republic

is manufactured under conditions fulfilling the quality system requirements of Annex VI, of the Directive 93/42/EEC as amended by 2007/47/EC.

The Notified Body No. 2265 has performed an audit of the above device quality system. The product quality assurance has been assessed and found that it meets the requirements above. The quality system is subject to continuous surveillance according to Annex VI, Sections 3.3, and 4, of the Directive 93/42/EEC as amended 2007/47/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. 310318, and the Final protocol No. 310318/2018.

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 October 15th, 2023 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfilment of relevant legal and other requirements by manufacturer.

Notified body · 3EC International · NB 2265 · NOTIFIKOVANÁ OSOBA

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

In Bratislava on October 16th, 2018