3EC®
international

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

EC CERTIFICATE

No. 2017-MDD/QS-037

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,

Medical Suction Unit
Type: MEVACS 40; MEVACS 40, MOD-1; MEVACS 50; MEVACS M20; MEVACS M20, MOD-1; MEVACS M30; MEVACS M30, MOD-1; MEVACS M38; MEVACS M38, MOD-1; MEVACS M46; MEVACS M46, MOD-1; MEVACS S30/30; MEVACS M20-230/12V; MEVACS M30-230/12V; MEVACS M90; MEVACS M20D; VACC-SPACE 20; VACC-SPACE 30; VACC-SPACE 50

manufactured by company

MEDIST, s.r.o.
Petrušovského 455/4, 066 01 Humenné, Slovak Republic

is manufactured under conditions fulfilling the quality system requirements of Annex V, 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 production quality assurance has been assessed and found that it meets the requirements above. The quality system is subject to continuous surveillance according to Annex V, 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. 310257, and the Final protocol No. 310257/2017 that is enclosed to this certificate.

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 July 29th, 2022 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 July 30th, 2017