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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
No. 2024-MDR/QS-019

Healthium Medtech Limited

Registered Place of Business: No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore, Karnataka – 560 058, India
Manufacturing Site 01: No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore, Karnataka – 560 058, India
SRN No.: IN-MF-000008421
Name and address of the Authorized representative:
MED DEVICES LIFESCIENCES B.V., Keizersgracht 482, 1017 EG Amsterdam, The Netherlands

This EU Quality Management System Certificate issued in accordance with the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended confirms, that quality management system of medical device:

Reusable Non-Sterile Instruments
(for detailed list refer to Annex I)
Intended purpose: Annex II
MD class Ir
(detailed list is stated in the annex(es) if applicable)

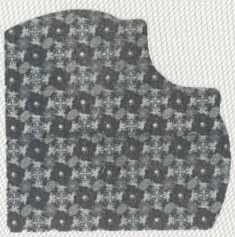
meets the requirements on quality management system according to the Chapter I and III of Annex IX of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended.

For class Ir devices, the audit by the NB2265 of the quality management system was limited to the aspects relating to the reuse of the MD, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related IFU.

Validity of the certificate is conditional upon positive results of regular surveillance audits.

Notified body No. 2265 has performed assessment of the quality management system of the abovementioned medical device and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the abovementioned medical device is stated in the MD Audit Report No. SK-0643-23/M from 02.02.2024. Information on all examinations and tests performed is stated in the abovementioned report and is available on request.

This **EU Quality Management System Certificate** applies only to the quality management system of the abovementioned medical device. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.



Valid from: **March 22, 2024**
Valid until: **March 22, 2029**
First issue: **March 22, 2024**
Revision: **00**
History: **Annex III**

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

3EC International a.s.
Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, March 22, 2024