



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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2023-MDR/QS-013

ROKIT HEALTHCARE Inc.

12F, Gasan High-hill Bldg., 9, Digital-ro 10-gil, Geumcheon-gu, Seoul, 08514 Republic of Korea

SRN No.: KR-MF-000009720

Name and address of the Authorized representative:

AR Experts B.V., Amerlandseweg 7, 3621 ZC Breukelen, 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:

Sterile Single-use Fat Separator

Dr. INVIVO AI Regen KIT

(detailed list is stated in Annex I)

Intended purpose: Annex II

MD class IIa

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.

Conditions for or limitations to the validity of the certificate: N/A

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 Technical Documentation Assessment Report No. MDR042_2021 from 12.04.2023, MD Clinical Evaluation Report No. MDR042_2021 from 12.04.2023 and MD Audit Report No. MDR042_2021 from 23.06.2023. Information on all examinations and tests performed is stated in the abovementioned reports 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: 03.07.2023
Valid until: 03.07.2028
First issue: 03.07.2023
Revision: 00
History: Annex III




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

In Bratislava, Slovakia, 03.07.2023