



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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-001

Karel Hrnčíř – BIOMAG

Chomutice 81, 507 53, Czech Republic
SRN No.: CZ-MF-000025009

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:

Pulsed Magnetic Therapy Device BIOMAG®

Models: BIOMAG® Lumina 3D-e with applicators (trade name: Lumina 3D-e), BIOMAG® Lumio 3D-e s applicators (trade name: Lumio 3D-e)

(see Annex I)

Intended purpose: Annex II

MD class IIa

(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.

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. MDR144_2022 from 19.11.2023, MD Clinical Evaluation Report No. MDR144_2022 from 24.11.2023 and MD Audit Report No. SK-0596-MDR/22 from 17.12.2023. 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: **31.1.2024**
Valid until: **31.1.2029**
First issue: **31.1.2024**
Revision: **00**
History: **Annex III**




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

In Bratislava, Slovakia, 31.1.2024