Number: 3903300CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Manufacturer:

FUSMobile Israel Ltd.

Etgar 4 St.
Tirat Carmel 3903215
Israel
SRN ID.: IL-MF-000037378

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 3902754CN

Authorized Representative: Donawa Lifesciense Consulting, Piazza Albania 10, Rome 00153, Italy

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M. McKenzie
Principal Certification Manager

First Issued: **12 May 2024** Date: **12 May 2024** Expiry date**: 1 May 2029**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

Number: 3903300CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

This certificate covers the following device(s) / groups of device(s):

INSTRUMENTS FOR ULTRASONIC SURGERY (Z120108, class IIb)	
Device Name: Neurolyser XR	*Intended Purpose: The Neurolyser XR is intended for thermal ablation of neural tissue (neurolysis), using non-invasive high intensity focused ultrasound (HIFU) with X-ray guidance.*

First Issued: **12 May 2024** Date: **12 May 2024** Expiry date**: 1 May 2029**

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Conditions for or limitations to the validity of this certificate:

- N/A

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	12-05-2024	3902754CN03	First issue

First Issued: **12 May 2024** Date: **12 May 2024** Expiry date**: 1 May 2029**

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