EU Quality Management System Certificate US25/00000108

The management system of

INVIA, LLC

3025 Boardwalk Drive, Suite 200, Ann Arbor, MI, 48108, United States Of America
SRN Number: US-MF-000008976

has been assessed and certified as meeting the requirements of

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

For the following products
The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 02 May 2025 until 18 March 2030 and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 18 March 2025

Authorised by
Virginie Siloret
Global Medical Device
Certification Manager
SGS Belgium NV NB1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
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EU Quality Management System Certificate US25/00000108, continued

INVIA, LLC

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

Class IIa devices:
MDA0315 MDS1010
Corridor4DM Nuclear Cardiac Quantification
Software Model: Corridor4DM v2018, Corridor4DM v2023, Corridor4DM v2024, Corridor4DM v2025
Basic UDI-DI: 08649740002C4DM10SR

Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available “on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on following reports: - WW/MD4/619868 – MED 1.15
Authorized representative name and address (if relevant): Emergo Europe ; Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands
Previous certificate number: N/A
Change in between this certificate and previous one: Addition of a new product "Corridor4DM v2025" to the scope.