EU Quality Management System Certificate GB23/00000417

The management system of

Invibio Device Component Manufacturing (IDCM) Ltd also Trading as Juvora Ltd

Technology Centre Hillhouse International Thornton-Cleveleys Lancashire FY5 4QD United Kingdom
SRN Number: GB-MF 000007895

has been assessed and certified as meeting the requirements of

MDR EU Quality Management System certificate (Annex IX QMS)

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

This certificate is valid from 27 March 2024 until 18 December 2028 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 18 June 2028
Issue 3. Certified since 18 December 2023

Authorised by
Virginie Siloret
Global Medical Device Certification Manager
SGS Belgium NV NB 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
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EU Quality Management System Certificate GB23/00000417, continued

Invibio Device Component Manufacturing (IDCM) Ltd also Trading as Juvora Ltd

MDR EU Quality Management System certificate (Annex IX QMS)

Class IIa device:
MDN 1103
JUVORA™ Dental Discs and CERAMILL PEEK by JUVORA™ Dental Discs
760410 Ceramill PEEK by JUVORA™ Natural
DD-95-16-03 JUVORA™ Natural Dental Disc
DD-98-30-02 JUVORA™ Oyster White Dental Disc
760393 Ceramill PEEK by JUVORA™ Oyster White
B-UDI: 50559482AAA0006C

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: - GB/PC/232837 - CTC 1.9
Authorized representative name and address (if relevant): MedEnvoy Global B.V ; Prinses Margietplantsoen 33 – suite 123 2595 AM The Hague The Netherlands
Previous certificate number: N/A
Change in between this certificate and previous one: Change of authorized representative