EU Quality Management System Certificate FR25/00000112

The management system of

IMPLANTS DIFFUSION INTERNATIONAL s.a.r.l.

23-25 rue Emile Zola, 93100 Montreuil, France

SRN Number: FR-MF-000000597

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 07 August 2025 until 12 May 2030 and remains valid subject to satisfactory surveillance audits.
Recertification audit due before 12 November 2029

Issue 2. Certified since 12 May 2025

Authorised by
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IMPLANTS DIFFUSION INTERNATIONAL s.a.r.l.

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

Class IIa devices:

MDN1208
Non-sterile surgical instruments with dental shank (Dental Cylindrical RBS Drills, Dental tapered RBS Drills, Dental Bladed Drills, Turbo Drill Bladed Tapered Drills).
Non-sterile surgical instruments with dental shank (thread taps, trephines, ridge spreaders, bladed wheels, instrument extension, guided surgery sleeve, screwdrivers).
[Basic UDI-DI: 03662174DENTALSHANKFP]

Class IIb devices:

MDN1103, MDS1005, EMDN: P01020101
Sterile dental implants (IDMax, IDCam, IDAll, IDBio, IDSlim, ID3);
[Basic UDI-DI: 03662174IMPLANTLU]
Sterile prosthetic components (closing cap, healing cap);
[Basic UDI-DI: 03662174SURGICALSCREWA3]

MDN1103, EMDN: P01020101
Non-sterile prosthetic components (closing cap, healing cap, abutments, attachments, tibase, transgingival element, screw);
Intended purpose: to replace missing teeth in the maxilla or mandible for prosthetic restoration: Unitary edentulous; Interleaf edentulous; Terminal edentulous; Total edentulous; Removable prosthesis stabilization.
[Basic UDI-DI: 03662174PROSTHETICHU

French translation of the scope
Dispositifs de classe IIa:

MDN1208
Instruments chirurgicaux non stériles pour pièce à main (Forets dentaires RBS cylindriques, Forets dentaires RBS coniques, Forets dentaires à lame, Forets turbo à lame conique).
Instruments chirurgicaux non stériles pour pièce à main (tarauds, trépans, expanseurscondenseurs, roues dentées, prolongateur d'instrument, douille pour chirurgie guidée, tournevis).
[Base UDI-DI: 03662174DENTALSHANKFP]

IMPLANTS DIFFUSION INTERNATIONAL s.a.r.l.

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

Dispositifs de classe IIb:

MDN1103, MDS1005, EMDN: P01020101
Implants dentaires stériles (IDMax, IDCam, IDAll, IDBio, IDSlim, ID3);
[UDI-DI de base: 03662174IMPLANTLU]
Composants prothétiques stériles (vis de fermeture, vis de cicatrisation);
[UDI-DI de base: 03662174SURGICALSCREWA3]

MDN1103, EMDN: P01020101
Composants prothétiques non stériles (vis de fermeture, vis de cicatrisation, attachement, piliers, tibase, manchon transgingival, vis).
Destination prevue: Pour remplacer les dents manquantes dans le maxillaire ou la mandibule dans le cadre d'une restauration prothétique: édentement unitaire; édentement intermédiaire; édentement terminal; édentement total; stabilisation de prothèses amovibles.
[UDI-DI de base: 03662174PROSTHETICHU]

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: - FR/MD/c236466 - S2A 1.1 + TFR 1.2 + TFR 1.5
Authorized representative name and address (if relevant): N/A
Previous certificate number: N/A
Change in between this certificate and previous one: Add to the scope: class IIb - Sterile dental implants & Sterile and Non-sterile prosthetic components.