EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HZ 1551305-1
Manufacturer:	ADSM SAS 7 RUE LAVOISIER 69680 CHASSIEU France
EUDAMED Single Registration No.:	FR-MF-000001222
Products:	Products of class IIb:

P09120301 - OSTEOSYNTHESIS DEVICES, DEVICES FOR TENDON AND LIGAMENT SYNTHESIS, KIRSCHNER BONE WIRES

P090603 - FOOT PROSTHESES INTERPHALANGEAL COMPONENTS, FOOT PROSTHESES

P09120601 - OSTEOSYNTHESIS DEVICES, DEVICES FOR TENDON AND LIGAMENT SYNTHESIS, CORTICAL SCREWS

P09120603 - OSTEOSYNTHESIS DEVICES, DEVICES FOR TENDON AND LIGAMENT SYNTHESIS, CANNULATED SCREWS

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.
If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.:	73084837-400
Effective date:	2025-06-30
Expiry date:	2026-10-12
Issue date:	2025-06-30

Rafał Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

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EU Certificate

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P09120604 - OSTEOSYNTHESIS DEVICES, DEVICES FOR TENDON AND LIGAMENT SYNTHESIS, OSTEOSYNTHESIS NAIL-SCREW SYSTEMS

Products of class IIa:

L091001 - INSTRUMENTS FOR INSERTION AND EXTRATION OF MATERIALS FOR OSTHEOSINTHESIS, REUSABLE

Z12130503 - ORTHOPAEDIC SURGICAL DRILLS

Products of class I, reusable surgical instruments:

L091201 - ORTHOPAEDIC SURGERY RASPS, REUSABLE

L091002 - INSTRUMENTS FOR PROCESSING MATERIALS FOR OSTHEOSINHESIS, REUSABLE

L091001 - INSTRUMENTS FOR INSERTION AND EXTRACTION OF MATERIALS FOR OSTHEOSYNTHESIS, REUSABLE

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EUDAMED Single Registration No.:	FR-MF-000001222
	L091303 - BONE REDUCTION FORCEPS, REUSABLE
	The scope of certification is limited to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.
Authorized representative(s):	Not applicable

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2021-10-13
1	Update of expiry date	2024-02-09
2	Scope extension	2024-07-24
3	Scope extension	2025-06-30

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