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 7b RUE LAVOISIER 69680 CHASSIEU France
EUDAMED Single Registration No.:	FR-MF-000001222
Products:	Class IIb medical devices: P091203 Bone fixation wires: - K-Wires with trocar tip, sterile - K-Wires with threaded tip, sterile - K-Wires with trocar tip, non-sterile - K-Wires with threaded tip, non-sterile P090603 Foot prostheses interphalangeal components: - TOEGRIP Classic - TOEGRIP Evo Class IIa medical devices: L091001 Instruments for insertion and extraction of osteosynthesis devices: - Partial threaded Guide-wires, sterile

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.:	73080276-100
Effective date:	2024-07-24
Expiry date:	2026-10-12
Issue date:	2024-07-24

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
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- Partial threaded Guide-wires, non-sterile

L1104 Drills and burs:
- Two-fluted drill bit with quick coupling Four-fluted cannulated drill bit with quick coupling, sterile
- Two-fluted drill bit with quick coupling Four-fluted cannulated drill bit with quick coupling, non-sterile
- Shannon burr, sterile
- Wedge burr, sterile
- Shannon burr, non-sterile
- Wedge burr, non-sterile

L1104 Drills and burs:
- Drill, non-sterile
- Milling tool (burr), non-sterile
- Compactor and reamer, non-sterile
- Calcar reamer, non-sterile
- Compactor, non-sterile

Class I devices, reusable surgical instruments:

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L0909 Orthopaedic surgery, cutting instruments:
- Tap, non-sterile
- Rasp, non-sterile

L091002 Instruments for osteosynthesis devices, preparation:
- Protective barrel, non-sterile

L091001 Instruments for insertion and extraction of osteosynthesis devices:
- Screwdrivers & screw extractors, non-sterile

L0399 General surgery instruments - others:
- AO handle, non-sterile

L091303 Forceps, bone reduction:
- Holder, Toe torn, non-sterile
- Reducer, non-sterile

L091099 Osteosynthesis instruments, reusable - others:
- Holder, non-sterile

The scope of certification is limited to the aspects relating to the reuse of the device, in particular cleaning, disinfection,

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	sterilization, maintenance and functional testing and the related instructions for use.
Authorized representative(s):	Not applicable

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

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