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 1789390-1
Manufacturer:	DESARROLLO E INVESTIGACION MÉDICA ARAGONESA, S.L. Polígono Industrial Mediavega, parcela 2.8 50300 Calatayud (Zaragoza) Spain
EUDAMED Single Registration No.:	ES-MF-000004008
Products:	Products of class IIa: U1299 - SINGLE-USE UROGENITAL INSTRUMENTATION (NON-ENDOSCOPIC) – OTHER Products of class IIb: P0899 - UROGENITAL PROSTHESES UROGENITAL PROSTHESES – OTHER Products of class III: P080199 - URINARY INCONTINENCE PROSTHESES URINARY INCONTINENCE PROSTHESES – OTHERS U070101 - INTERNAL SYSTEMS FOR THE TREATMENT OF INCONTINENCE SLING SYSTEMS FOR THE TREATMENT OF INCONTINENCE

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.:	92700573-30
Effective date:	2024-04-25
Expiry date:	2028-05-07
Issue date:	2024-04-25

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.

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Authorized representative(s):	Not applicable

Certificate history		
Revision:	Description:	Issue date:
1	Initial certification	2023-05-08
2	Scope extension for products of class IIb	2024-03-20
3	Correction of the manufacturer name	2024-04-25

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