

EU Certificate

Quality Management System REGULATION (EU) 2017/745 on Medical Devices Annex IX Chapters I and 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 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.: 92797528-130

Effective date: 2026-09-25

Expiry date: 2028-05-07

Issue date: 2026-09-25



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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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P0899 - UROGENITAL PROSTHESES
UROGENITAL PROSTHESES – OTHER

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
3	Scope extension for EMDN code: P0899 – UROGENITAL PROSTHESES – OTHER	2026-08-31
4	Correction of the certificate revision number for scope extension for EMDN code: P0899 – UROGENITAL PROSTHESES – OTHER compared to the previous version of the certificate.	2026-09-25

