EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1960556-1

Manufacturer:
APIS TECHNOLOGIES SARL
Rue de l'Ouriette 141
1170 Aubonne
Switzerland

Products:
- Sling and kits for female stress urinary incontinence treatment with instruments
- Kits for male stress urinary incontinence treatment with slings and instruments
- Pelvic organ prolapse surgical meshes

Replaces EC Certificate number HD 60149003 0001

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 73077302-100

Effective date: 2021-05-24

Expiry date: 2024-05-26

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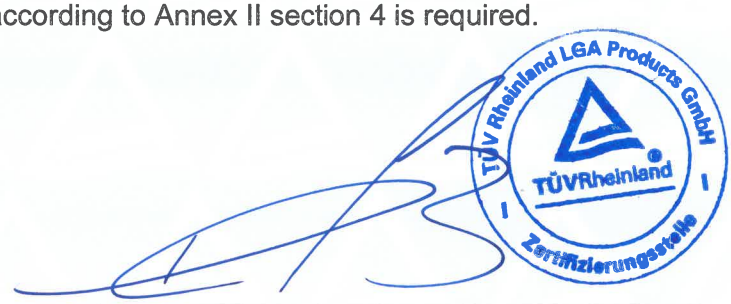

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.