



EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G11 106145 0005 Rev. 00

Manufacturer: **Pregnoia AG**

Wiesenstrasse 33
8952 Schlieren
SWITZERLAND

SRN Manufacturer - CH-MF-000033377

**Authorized
Representative:**

MT Promedt Consulting GmbH
Ernst-Heckel-Straße 7, 66386 St. Ingbert, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. As applicable the involvement of the notified body is limited to the aspects relating to:

- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G11 106145 0005 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G11_106145_0005_Rev.00)

Report No.: 713303617

Valid from: 2023-12-21

Valid until: 2028-12-20

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-12-21



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Classification: Class I (Annex XVI)
Device Group: V030205 - OBSTETRICS AND GYNECOLOGY MEASUREMENT DEVICES NOT INCLUDED IN OTHER CLASSES
Device Properties: MDS 1010 - Devices with a measuring function

Classification: Class I (Annex XVI)
Device Group: V030205 - OBSTETRICS AND GYNECOLOGY MEASUREMENT DEVICES NOT INCLUDED IN OTHER CLASSES
Device Properties: MDS 1005.1 - Ethylene Oxide sterilization

The validity of this certificate depends on conditions and/or is limited to the following: -none-

Revision History:

Rev.	Dated	Report	Description
00	2023-12-21	713303617	Initial issuance