



## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

**No. G10 110943 0002 Rev. 02**

### Manufacturer:

**Esco Medical Technologies UAB**

Gamybos g. 2  
Ramučiai  
54468 Kauno r.  
LITHUANIA

SRN Manufacturer - LT-MF-000010902

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.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.

For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G10 110943 0002 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:G10_110943_0002_Rev.02)

<b>Report No.:</b>	713330320
<b>Preceding Certificate No.:</b>	G10 110943 0002 Rev. 01
<b>Valid from:</b>	2024-06-13
<b>Valid until:</b>	2027-09-01
<b>Date of Initial Issuance:</b>	2022-09-02

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2024-06-13



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**Classification:** Class IIa  
**Device Group:** Z120802 - GYNAECOLOGY AND FERTILITY TREATMENT INSTRUMENTS  
**Intended Purpose:** ./.

**Classification:** Class IIa  
**Device Group:** W050304 - CELL AND TISSUE CULTURES DEVICES  
**Intended Purpose:** ./.

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

### Revision History:

Rev.	Dated	Report	Description
00	2022-09-02	713198822	-
01	2022-11-22	713198822_CN_CultureCoin-	-
02	2024-06-13	713330320	Amended: Change of certificate holder's data