

Certificate

acc. to **ISO 13485:2016**

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: **21-1602-M**

TUV USA, Inc. hereby certifies that the quality management system of the company mentioned below is in conformance with ISO 13485:2016 under MDSAP for Medical Devices Requirements under the following jurisdictions:

Canada: Medical Devices Regulations – Part 1- SOR/98-282. **USA:** United States: 21 CFR 803; 21 CFR 806; 21 CFR 807 – Subparts A to D; 21 CFR 820.

Enbio Group AG
4702 Oesingen, Switzerland

Facility ID: **F005513**

Additional sites covered by QM System: [See Annex 1](#)

List of Products: [See Annex 2](#)

Scope:

Design, manufacture, distribution, and service of small steam sterilizers

The validity of this certification document can be obtained by contacting the TUV USA, Inc. Office.

TUV USA, Inc. (a Member of the TÜV NORD Group)

215 Main Street, Suite 1, Salem, NH 03079, USA

Tel: 001-603-870-8023, Fax: 001-603-870-8026, Email: medical-usa@tuv-nord.com

TUV USA, Inc. is an MDSAP Recognised Auditing Organization



Audit Report Reference No.: **21-3940 CA**

Certificate Initial Issue Date: **2022-02-08**

Current Cycle Start Date: **2022-02-08**

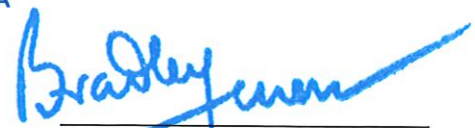
Certificate Revised Date: **N/A**

Effective Date:

2022-02-08 / ed. 1

Valid Until:

2025-02-07



Bradley Chen
Vice President – Medical, Americas
Medical Products Division
TUV USA, Inc.

Certificate Registration No. : 21-1602-M / ed. 1
Company Name: Enbio Group AG
Central Office Address: 4702 Oesingen, Switzerland



Location

Scope of Certification

Facility ID: F005513
Headquarters
Enbio Group AG
Eichengasse 3
4702 Oesingen, Switzerland

Final assembly, validation, packaging / shipping to distribution

Facility ID: F005514 (Campus)
Site 2
Enbio Technology Sp. z o. o.
Sportowa 8C
Gdynia 81-300, Poland

Design and development, manufacture, distribution, and service

Site 1
Enbio Technology Sp. z o. o.
Dzialkowcow 15
Rumia 84-230, Poland

Design and development, manufacture, distribution, and service

---End of list---

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Annex 2, page 1 of 1
(Annex 2 MUST be displayed with the main certificate)

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Central Office Address: 4702 Oesingen, Switzerland



Products	UMDNS	GMDN
Small steam sterilizers	16-142	38671

---End of list---

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