



EC Declaration of Conformity

Manufacturer **ENBIO GROUP AG, Eichengasse 3 Street, 4702 Oensingen, Switzerland,**

having: Enbio Technology Sp. z o. o., Sportowa 8C Street, 81-300 Gdynia, Poland, as an European Authorized Representative,

declares with sole responsibility, that medical devices: **STEAM STERILIZERS**, models:

- **Enbio S**
- **Enbio PRO**
- **Enbio XS**

complies with provisions of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (as amended). The device has been classified in Class IIb in accordance with rule 15 of Annex IX of the above mentioned Directive.

Conformity assessment has been carried out in accordance with Annex II without point 4 of the above Regulations.

The conformity assessment has been conducted by the Notified Body No. 2274

TUV Nord Polska Sp. z o.o.

Mickiewicza 29 Street

40-085 Katowice

Poland



Sebastian Magrian

A handwritten signature in blue ink, appearing to read 'S. Magrian'.

Oensingen

26.04.2021

Managing Director

President of the Board