

10. DICHIARAZIONE DI CONFORMITÀ



EC Declaration of Conformity

Company: Enbio Group AG, Eichengasse 3, 4702 Oensingen, Switzerland

declares with sole responsibility, that medical devices: **STEAM STERILIZER**
(model):

ENBIO S

ENBIO PRO

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

ul. A. Mickiewicza 29, 40-085 Katowice, Poland



Sebastian Magrian

Simon Schaefer

Oensingen
17.01.2020

President of the
Board of Directors

Member of the Board