

## EC Declaration of Conformity

Company: **ENBIO Group AG**  
**Eichengasse 3, 4702 Oensingen, Switzerland**

declares with sole responsibility, that medical device (model):

**STEAM STERILIZER STEAMJET**

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.3 of the above Regulation. In the conformity assessment the following standards have been used:

**EN 13060:2014**  
**EN ISO 15223-1:2016**  
**EN ISO 14971:2012**  
**EN 62366:2008**  
**EN 61010-2-040:2015**  
**EN 13485:2016**

**EN ISO 17665-1:2006**  
**EN 62304:2006+A1:2015**  
**EN 1041:2008+A1:2013**  
**EN 61010-1:2010**  
**EN 61326-1:2013**

The conformity assessment has been conducted by the Notified Body No 2274  
TUV Nord Polska Sp. z o.o.  
Str. A. Mickiewicza 29; 40-085 Katowice, Poland



Place and date:  
**Oensingen, 01.02.2019**

Signatures and company stamp:

**Enbio Group AG**

Hans Peter Mark  
President of the Board  
Enbio Group AG