

DECLARATION OF CONFORMITY

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Classification: class I

We herewith declare that the above mentioned product meet the provisions of the following EC Council Directives and its implementation in national law. All supporting documentation are retained under the premise of manufacturer.

Directives: Medical Device Directive 93/42/EEC as amended with

2007/47/EC, Annex V

Standard applied: harmonized standards published in the official journal of the

European communities applicable to this product.

Chiasso, 01.01.2020

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