ForaCare Suisse AG

EU Declaration of Conformity

We, ForaCare Suisse AG,

Neugasse 55, 9000 St. Gallen, Switzerland

as Legal Manufacturer, declare under our sole responsibility that the product

Product Name	:	Telehealth System
Product Model	:	Telehealth System
Classification	:	MDD 93/42/EEC (amended with 2007/47/EC), Annex IX, Section 1, Rule 1, Class I
Conformity Assessment Route	:	MDD 93/42/EEC (amended with 2007/47/EC), Annex VII
CE Mark	:	**CE**
GMDN Code	:	57967

to which this declaration relates is in conformity with the following standard(s) or other normative document(s)：

EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN 1041:2008 +A1:2013	Information supplied by the manufacturer of medical devices.
EN ISO 15223-1:2016	Medical devices-Symbols to be used with medical device labels, labelling and information to be supplied - Part1: General requirements
93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

The objective of the declarations above is to conform that above-mentioned product(s) meet the provisions of the “Council Directive 93/42/EEC of 14 June 1993 concerning medical devices”.

St. Gallen, February 27, 2020
Place, Date of Issue

Ty-Minh Tan, C.E.O.