

# Declaration of conformity

Sananet

Declaration number: 20210408

The manufacturer: Sananet Care BV  
Stationsplein 5d  
6131 AT Sittard  
The Netherlands

Declare that the product: SananetOnline  
(NL-CA002-2019-46231)

Is conform to the following directives and standards:

## Medical Device Directives (MDD) 93/42/EEC of 14 June 1993 concerning medical devices

The following relevant harmonized standards have been applied:

Number	Version	Title
NEN-EN-ISO 9001	2015	Quality management systems
IEC 62304	2006	Medical device software – Software life-cycle processes IEC 62304: 2006 + Correction AC:2008
ISO 14971	2019	Medical devices - Application of risk management to medical devices
NEN-EN-IEC 82304-1	2017	Health Software - Part 1: General requirements for product safety

We declare that the CE marked products mentioned in the certificate meet the applicable provisions of the European Community Directive for Class I devices.

This declaration of conformity is issued under the exclusive responsibility of the manufacturer

Place: Sittard, the Netherlands

Date: 9 april 2021

Sananet Care BV  
Jan Ramaekers  
CEO

