

Declaration of Conformity MDD

ID. 1103-023
Rev. 03
Status Final
Effective 18-May-2022



Quirem Medical B.V.
Zutphenseweg 55
7418 AH Deventer
The Netherlands

DECLARATION OF CONFORMITY

medical devices

We hereby declare under our sole responsibility that the distributed CE marked products, specified hereafter, meet the provisions of the Dutch “Besluit Medische Hulpmiddelen”, being the transposition of the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices, which apply to them.

This declaration is based on the application of a Quality Management System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex II of the EC-Directive, and is described in the CE Marking of Conformity Certificate, reference number: 2172702CE02, issued on 06-Aug-2020 and delivered by DEKRA Certification B.V.

This declaration is supported by the Quality Management System certification based on the harmonized standard EN ISO 13485:2016, Quality Management System Certificate with reference number: 2172692, issued on 01-April-2022 and delivered by DEKRA Certification B.V.

This Declaration of Conformity covers the Q-Suite® product family and is valid for all products concerned bearing the CE marking, as specified hereafter:

Product Name : Q-Suite® 1.2 MDD Class Im

Product Name : Q-Suite® 2.0 MDD Class IIb

Product Name : Q-Suite® 2.1 MDD Class IIb

Deventer, date: 18-MAY-2022

Laurent Domas
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