Declaration of Conformity AIMDD

ID.	1101-014
Rev.	06
Status	Final
Effective	12-April-2018

Quirem

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 below, conform to the products covered by the EC Design-Examination Certificate, reference number : 2172702DE01, issued on 01 April 2018 and delivered by DEKRA Certification B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344, according to the provisions of Annex 2 of the "EC-Directive", the Council Directive 90/385/EEC of 20 July 1990, concerning active implantable medical devices.

In addition, we ensure and declare that the distributed CE marked products, as mentioned, meet the provisions of the EC-Directive 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 2 of the EC-Directive, and is described in the CE Marking of Conformity Certificate, reference number:2172702CE01, first issued on 01 April 2018, re-issued on 01 April 2018 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 2018 by DEKRA Certification B.V.

This Declaration of Conformity covers the QuiremSpheres® and is valid for all products concerned bearing the CE marking, as specified hereafter.

Product Code	Product name
QS-V001	QuiremSpheres®, holmium-166 PLLA microspheres

Deventer, 12 April 2018

John Mittendorf
Quality Assurance & Regulatory Affairs Manager