DECLARATION OF CONFORMITY

medical devices

We hereby declare that the distributed CE marked products, specified in the annexed product list, confirm to the Council Directive 93/42/EEC of 14 June 1993 and 2007/47/EG of 5 September 2007, concerning medical devices.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class IIb, meet the provisions of the EC-Directive which apply to them.

This declaration is based on the application of the Full Quality Assurance System approved for products concerned, in accordance with Annex II of the EC-Directive. The conformity of the production quality assurance set out in Annex II, is described in the CE Marking of Conformity Certificate, reference number: **2117262CE01** and delivered by DEKRA Certification B.V., first issued on September 9th, 2008.

This declaration is supported by the Quality System certification based on the harmonized standard ISO 13485:2016, Quality System Certificate with reference number: **2117262** and delivered by DEKRA Certification B.V., first issued on September 9th, 2008.

This Declaration of Conformity covers the **Noviomagus Revision Mesh** as specified in the product list belonging to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at the following site(s):

Spierings Orthopaedics B.V.
Madoerastraat 24
6524 LH Nijmegen
The Netherlands

Nijmegen, 27 July 2018

P. T. J. Spierings, MD, Msc
Managing Director

Annex: Product list PRL-HRS001