

Declaration of conformity  
(Annex VII, Class I)

## DECLARATION OF CONFORMITY

medical devices

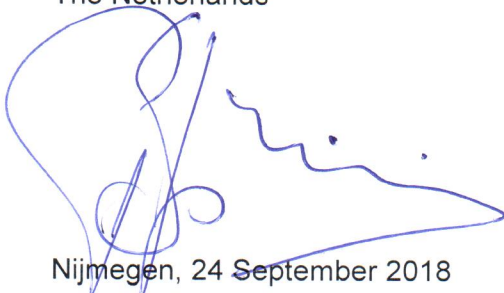
We hereby declare that the distributed CE marked products, specified in the annexed product list, **PRL-HRS002**, are covered by Annex VII of the "EC-Directive", the Council Directive 93/42/EEC of June 14<sup>th</sup> 1993 and 2007/47/EC of September 5<sup>th</sup> 2007, concerning medical devices.

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

This declaration is supported by the Quality System certification based on the standard ISO 13485:2016, Quality System Certificate issued by DEKRA Certification B.V. with reference number: **2117262**, initially issued on September 9<sup>th</sup>, 2008.

This Declaration of Conformity covers the **Noviomagus BIG Instrumentation** 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, 24 September 2018

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

Annex: Product list PRL-HRS002