DECLARATION OF CONFORMITY

medical devices

We hereby declare that the distributed CE marked products, specified in the annexed productlist, confirm to the design(s) covered by the EC Design-Examination Certificate, reference number: 2117262DE02, issued on October 15th, 2010 and delivered by DEKRA Certification B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344, in accordance with Annex II of the "EC-Directive", the Council Directive 93/42/EEC of June 14th 1993 and 2007/47/EC of September 5th 2007, concerning medical devices.

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

This declaration is based on the application of the Quality System approved for the manufacture and final inspection of the 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, issued on September 9th, 2008 and delivered by DEKRA Certification B.V.

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 9th, 2008.

This Declaration of Conformity covers the **REX Cement Stop** as specified in the product list belonging to this declaration, and is valid for all the 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 January 2019
P. T. J. Spierings. MD, Msc
Managing Director

Annex: Product list PRL-FBP001