DECLARATION OF CONFORMITY

medical devices

We hereby declare that the distributed CE marked products, specified in the annexed product list **PRL-BHS001**, are covered by Annex VII 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 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 9th, 2008.

This Declaration of Conformity covers the **Bone Harvesting System** 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:

Spierings Orthopaedics B.V.
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6524 LH Nijmegen
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Nijmegen, 24-Sep-2018
P. T. J. Spierings, MD, MSc
Managing Director

Annex: Product list PRL-BHS001