

## DECLARATION OF CONFORMITY

medical devices

We hereby declare that the distributed CE marked products, specified in the annexed product list **PRL-SBM003**, are covered by Annex VII of the "EC-Directive", the Council Directive 93/42/EEC of 14 June 1993 as amended by 2007/47/EC, 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 09 September 2008.

This Declaration of Conformity covers the **Noviomagus Bone Mill**, **Noviomagus Mini Mill** and **Noviomagus Micro Mill** 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:

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6524 LH Nijmegen  
The Netherlands

Nijmegen, 27 July 2018

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

Annex: Product list PRL-SBM003