DECLARATION OF CONFORMITY

medical devices

We hereby declare that the distributed CE marked products, specified in the annexed product list, confirm to the type(s) covered by the EC Type-Examination Certificate, reference number: **2117262TE01**, issued on June 16th, 2010 and delivered by DEKRA Certification B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344, in accordance with Annex III of the "EC-Directive", 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 Quality System approved for the manufacture and final inspection of the products concerned, in accordance with Annex V of the EC-Directive. The conformity of the production quality assurance set out in Annex V, coupled with the procedure set out in Annex III, 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 harmonized standard ISO 13485:2003, Quality System Certificate with reference number: **2117262**, issued on September 9th, 2008 and delivered by KEMA Quality B.V.

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, February 1st, 2011

Ing. B.F.M.J. de Backer
Quality Manager

Annex: Product list PRL-HRS001