

EU DECLARATION OF CONFORMITY

Manufacturer: Spierings Orthopaedics B.V.
Madoerastraat 24
6524 LH Nijmegen
The Netherlands

Single registration number (SRN): NL-MF000023199

Basic UDI-DI: 872025400NFHRS9U

Name of device: Noviomagus Femoral Head Reamer Set

Product code: SBM

Classification: I

This declaration is issued under the sole responsibility of Spierings Orthopaedics B.V.

We declare that the products, as specified in the annexed product list, that are covered by this declaration are in conformity with Regulation (EU) 2017/745 (MDR).

This declaration is based on the application of the Quality System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex I and III of Regulation (EU) 2017/745 (MDR).

This declaration is supported by the Quality System certification based on the standard ISO 13485:2016, Quality System Certificate with reference number: **2117262** initially issued on 09 September 2008 and delivered by DEKRA Certification B.V.

Nijmegen, 14-March-2024
P.T.J. Spierings
Managing Director



Annex: Product list PRL-SBM002

Declaration of Conformity (NFHRS)

Author: B. Pater
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