

## EU DECLARATION OF CONFORMITY

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

**Single registration number (SRN):** NL-MF-000023199

**Basic UDI-DI:** 8720256027NFHRS5M

**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

<b>Declaration of Conformity (NFHRS)</b>	
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