

DECLARATION OF CONFORMITY

Declaration of Conformity based on the requirements of Annex XIII of the Medical Devices Regulation (MDR (EU) 2017/745).

ZSM Orthopedics BV

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ORTHOPEDICS

Prescriber medical device:

- Name of physician/ therapist:
 - Organization/institution:
 - Specific product specifications:
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- Characteristics:

Device identification:

The medical device supplied is a custom-made medical device and the respective orthopedic custom shoes is only intended for use by:

- Name customer:

Declaration of conformity with the General Safety and Performance Requirements:

This declaration of conformity is issued under the sole responsibility of ZSM Orthopedie BV.
The custom-made medical device described in this statement complies with the General Safety and Performance Requirements (GSPR) as laid down in Annex I, MDR 2017/745

Place name:

Date:

On behalf of prescriber:

Signature:

Name:



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