

# Declaration of conformity for Medical Devices

**Maxxcare BV  
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1531 AX Wormer**

**T**his declaration of conformity is issued under the sole responsibility of Maxxcare. We hereby declare that the Class 1 medical devices specified in the attached product list meet the provision of the Medical Device Regulation (EU) MDR 2017/745. This declaration is supported by the Quality System approval to ISO 13485 issued by DEKRA Certification B.V.

All supporting documentation is retained at the premises of the manufacturer.

Details of the products are laid down in the Technical File, which is present at the above mentioned address. The Technical File complies with the requirements of the Medical Device Regulation (EU) MDR 2017/745.



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Date: 10-05-2021  
Wormer

**M. Rogmans**  
CEO



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Date: 10-05-2021  
Wormer

**L. Wagemans**  
Quality Manager

# Product List

## Annex to Declaration of Conformity

For products of the category: Class I according to MDR2017/745, Annex VIII

### Standard models with Basic-UDI:

#### Heel Protector Pro Evolution - 8717545MAX001WU

Heel Protector Pro Evolution Small size (Small)

Heel Protector Pro Evolution Standard size (ST)

Heel Protector Pro Evolution Xlarge size (XL)

#### Intended use:

Heel Protector Pro Evolution is intended to equally distribute pressure and offer protection in the heel area.

### Special or non-current models:

#### Name of the product

Heel Protector

#### Available variants (sizes in cm)

Standard size (ST) & Xlarge size (XL)

#### Change(s):

Rev. 01: Basic-UDI added