



Nimco Made4You B.V.
Oude Kleefsebaan 119
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The Netherlands

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EC Declaration of Conformity for medical products according to Regulation (EU) 2017/745

Manufacturer:

Nimco Made4You B.V.
Oude Kleefsebaan 119
6572 AK Berg en Dal
THE NETHERLANDS
Tel. +31 (0) 24 – 684 8090
Email: info@nm4y.com Internet: www.nm4y.com

Product name:

Specialty footwear for diabetic patients

Ladies models: 7006 Sharon Lace, 7004 Ilse Lace, 7006 Irma Lace, 7102 Ilke Velcro, 7000 Ingrid Velcro, 7102 Polish Velcro, 7203 Claudia Lace, 7201 Isa, 70051 Caroline Velcro

Men's models: 7504 San Francisco, 7700 Brave Lace, 7700 Brave Velcro, 7701 Challenger, 7702 Traveler Lace, 7503 Sailor Lace, 7503 Sailor Velcro, 7501 Orlando Lace, 7501 Orlando Velcro, 7502 New York, 7602 Olav Velcro, 70017 Chris Lace

Base UDI: 87202995081NM4Y4A

Classification:

According to the classification rule according to Annex VIII which are Class I medical devices.

Declaration

We hereby declare that the Class I medical devices listed above comply with the basic requirements of Annex I of the MDR regulation EU 2017/745 and assume sole responsibility for the issue.

The declaration of conformity was made in accordance with Annex IV of the MDR regulation EU 2017/745.

The standard materials comply with Regulation (EC) No. 1907/2006 REACH, are SG-tested, some with a biocompatibility test. Our management system is certified according to DIN EN ISO 9001: 2015. The documentation of the production is available and is updated continuously.

Company stamp

place, date

O.J.A. Toornend

Nimco Made4you
Oude Kleefsebaan 119
6572 AK BERG EN DAL

Berg en Dal, 19.05.2021

Qualified Person