

EU Declaration of Conformity

I. Product model/product:

Product name: Footcare products
Model number: See Attachment
Trade name: Vital Comfort footcare, see attachment
Classification (MDD Annex IX): Class I, rule 1
UMDNS: 11-095

II. Manufacturer/supplier name

Name: GHZ Matra AG
Address: Max-Volmer-Str. 14, 40724 Hilden (Germany)

III. Name of the company & quality management representative

Company: GHZ Matra AG
Safety officer: Claudia Küpper

IV. Conformity with the relevant Union harmonization and standards

We herewith declare that the above mentioned products meet the following EC Council Directives and Standards. General applicable directives: Medical device directive: Council Directive 93/42/EEC of June 1993 concerning medical devices (MDD 93/42/EEC. Amended by Directive 2007/47/EC of 5 September 2007 with its product classification MDD Annex IX, I rule 1, approach of product conformity, Annex V.3 & Annex VII.3

Notified body and certified Quality Management System ISO 13485 of the manufacturer is NQA Certification Co. Ltd, certificate No. 45410, expire date of the certificate 2021-10-17.

Signature: 
Name: Claudia Küpper
Position: Safety officer

Place, Date of issue: Hilden, 25 February 2020

Annex I rev. 3:

List of footcare products, UMDNS 11-095, GMDN code for footcare products 09

Model number	Trade name	Product description	Classification
114669 /HL-003/N-300035	Vital Comfort toe spreader 3 pcs	See Technical files	MDD 93/42 EEC, Annex IX, class I, rule I
114673/HL-001	Vital Comfort toe separator 1 pair	See Technical files	MDD 93/42 EEC, Annex IX, class I, rule I
114462/HL-020 63-0767-1 GR.:01	Vital Comfort Toe Spreader (for all toes) set of 2	See Technical files	MDD 93/42 EEC, Annex IX, class I, rule I
114664/N-300030 /HL-017 63-0768-8 GR.:01	Vital Comfort finger and toe protection, 2 pcs each	See Technical files	MDD 93/42 EEC, Annex IX, class I, rule I
114670/N-300036/HL-011	Vital Comfort heel protection shoe pads 4 pcs.	See Technical files	MDD 93/42 EEC, Annex IX, class I, rule I
114754	Vital Comfort metatarsal pad 2 pcs	See Technical files	MDD 93/42 EEC, Annex IX, class I, rule I
114665/N-300031/HL-018	Vital Comfort ball of foot protection 1 pair size S/M	See Technical files	MDD 93/42 EEC, Annex IX, class I, rule I

GHZ Matra AG

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GHZ Matra AG • Max-Volmer-Str. 14 • 40724 Hilden (Germany)

Vorstand: Dr. Jochen Riemen • Vorsitzender des Aufsichtsrates: Franz Robens

Sitz: Hilden • Handelsregister: AG Düsseldorf HRB 46306 • USt-ID: DE 812 477 545 • ILN: 42 500079 0000 1 • WEEE Reg.Nr.: DE 62364351
Commerzbank AG, Hilden (BLZ 300 400 00, SWIFT/BIC: COBA DE DXXX) • Konto: 65 10 630 • IBAN: DE95 3004 0000 0651 0630 00

114667/HL-012/N-300033	Vital Comfort Hallux Valgus protection size S/M	See Technical files	MDD 93/42 EEC, Annex IX, class I, rule I
114761	Vital Comfort Shoe Pads for Heels, 4 pairs	See Technical files	MDD 93/42 EEC, Annex IX, class I, rule I
114662/N-300028/HL-013	Vital Comfort heel sock size S/M	See Technical files	MDD 93/42 EEC, Annex IX, class I, rule I
114668/HL-012/N-300034	Vital Comfort Hallux Valgus protection size L/XL	See Technical files	MDD 93/42 EEC, Annex IX, class I, rule I
114666/ N-300032/HL-018	Vital Comfort ball of foot protection 1 pair size L/XL	See Technical files	MDD 93/42 EEC, Annex IX, class I, rule I
114663/N-300029/HL-013	Vital Comfort heel sock size L/XL	See Technical files	MDD 93/42 EEC, Annex IX, class I, rule I
110703/HG-10	Vital Comfort Heel Cushion 1 Pair blue	See Technical files	MDD 93/42 EEC, Annex IX, class I, rule I
114994/HL-021	Vital Comfort Hallux Valgus protection and toe spreader	See Technical files	MDD 93/42 EEC, Annex IX, class I, rule I
115071/115072	Vital Comfort Heel Spur Cushion – women/men	See Technical files	MDD 93/42 EEC, Annex IX, class I, rule I

Place, Date of issue: Hilden, 25.02.2020

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