



Declaration of Conformity

Manufacturer: Mediroyal Nordic AB
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SRN number: SE-MF-000007821

GMDN code: 41457

EMDN code: Y060606

Product model/version: 903

Product: Edema Glove

Risk class according to annex VIII: Class 1


Conformity route: Annex IV (class I product)

Intended purpose: An interim edema glove to provide compression to the wrist and fingers.

Expiry date: 10 years from production date on LOT/batch code.

This EU declaration is issued under the sole responsibility of the manufacturer and we hereby assure that the product above is in accordance with the Medical Device Regulation 2017/745.

Sollentuna 2022-03-31



Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329903M3	-	903XSL	LT/XS Edema Glove
73400329903M3	-	903SL	LT/S Edema Glove
73400329903M3	-	903ML	LT/M Edema Glove
73400329903M3	-	903LL	LT/L Edema Glove
73400329903M3	-	903XSR	RT/XS Edema Glove
73400329903M3	-	903SR	RT/S Edema Glove
73400329903M3	-	903MR	RT/M Edema Glove
73400329903M3	-	903LR	RT/L Edema Glove