CE

Declaration of Conformity

Manufacturer:	Mediroyal Nordic AB Staffans väg 6B SE-192 07 Sollentuna Telephone: +46 8 506 766 00 Fax: +46 8 506 766 90 Email: info@mediroyal.se Webb: www.mediroyal.se
SRN number:	SE-MF-000007821
GMDN code:	41457
EMDN code:	Y060606
Product model/version:	NRX201
Product:	NRX Thumb Short
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	A light joint support for the thumb, adjusted individually by the therapist over the thumb to provide support.
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 2022-03-10

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329NRX201EP	-	NRX201-L1	LT XS/S NRX Thumb Short
73400329NRX201EP	-	NRX201-L2	LT M/L NRX Thumb Short
73400329NRX201EP	-	NRX201-R1	RT XS/S NRX Thumb Short
73400329NRX201EP	-	NRX201-R2	RT M/L NRX Thumb Short