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:	41461
EMDN code:	Y060613
Product model/version:	MR2285
Product:	NRX Manex Radial
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	A joint support for the wrist, applied over the wrist joint to provide extension to the MCP, thumb and wrist.
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 2022-03-03

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329MR228577	MR2285-LXS	MR02285100309	LT/XS NRX Manex Radial
73400329MR228577	MR2285-LS	MR02285100409	LT/S NRX Manex Radial
73400329MR228577	MR2285-LM	MR02285100509	LT/M NRX Manex Radial
73400329MR228577	MR2285-LL	MR02285100609	LT/L NRX Manex Radial
73400329MR228577	MR2285-LXL	MR02285100709	LT/XL NRX Manex Radial
73400329MR228577	MR2285-RXS	MR02285200309	RT/XS NRX Manex Radial
73400329MR228577	MR2285-RS	MR02285200409	RT/S NRX Manex Radial
73400329MR228577	MR2285-RM	MR02285200509	RT/M NRX Manex Radial
73400329MR228577	MR2285-RL	MR02285200609	RT/L NRX Manex Radial
73400329MR228577	MR2285-RXL	MR02285200709	RT/XL NRX Manex Radial