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:	41465
EMDN code:	Y060621
Product model/version:	NRX950
Product:	ErixFour Shoulder Brace
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To support the shoulder both mechanical and proprioception as well as creating a posterior safe position of the shoulder. The additional straps can be used both for suspension of the shoulder joint as well as proprioceptive feedback.
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 2025-10-14

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329NRX950G7	-	NRX950-LXS	ErixFour Shoulder Brace Left XS
73400329NRX950G7	-	NRX950-LS	ErixFour Shoulder Brace Left S
73400329NRX950G7	-	NRX950-LM	ErixFour Shoulder Brace Left M
73400329NRX950G7	-	NRX950-LL	ErixFour Shoulder Brace Left L
73400329NRX950G7	-	NRX950-LXL	ErixFour Shoulder Brace Left XL
73400329NRX950G7	-	NRX950-RXS	ErixFour Shoulder Brace Right XS
73400329NRX950G7	-	NRX950-RS	ErixFour Shoulder Brace Right S
73400329NRX950G7	-	NRX950-RM	ErixFour Shoulder Brace Right M
73400329NRX950G7	-	NRX950-RL	ErixFour Shoulder Brace Right L
73400329NRX950G7	-	NRX950-RXL	ErixFour Shoulder Brace Right XL

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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:	CGO208
Product:	NRX C-GO Thumb
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	A 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 2025-06-17

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329CGO2084W	-	CGO208-L1	LT/XS NRX C-GO Thumb
73400329CGO2084W	-	CGO208-L2	LT/S-M NRX C-GO Thumb
73400329CGO2084W	-	CGO208-L3	LT/L-XL NRX C-GO Thumb
73400329CGO2084W	-	CGO208-L4	LT/XXL NRX C-GO Thumb
73400329CGO2084W	-	CGO208-R1	RT/XS NRX C-GO Thumb
73400329CGO2084W	-	CGO208-R2	RT/S-M NRX C-GO Thumb
73400329CGO2084W	-	CGO208-R3	RT/L-XL NRX C-GO Thumb
73400329CGO2084W	-	CGO208-R4	RT/XXL NRX C-GO Thumb

Doc. no:	MR2381-05
Version:	5.0

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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:	MR2381
Product:	Proxi CMC
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	A stable joint support for the thumb, applied over the thumb to provide support to the CMC joint.
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 2022-03-25

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329MR238174	MR2381-LXS	MR02381100309	LT/XS Proxi CMC
73400329MR238174	MR2381-LS	MR02381100409	LT/S Proxi CMC
73400329MR238174	MR2381-LM	MR02381100509	LT/M Proxi CMC
73400329MR238174	MR2381-LL	MR02381100609	LT/L Proxi CMC
73400329MR238174	MR2381-LXL	MR02381100709	LT/XL Proxi CMC
73400329MR238174	MR2381-RXS	MR02381200309	RT/XS Proxi CMC
73400329MR238174	MR2381-RS	MR02381200409	RT/S Proxi CMC
73400329MR238174	MR2381-RM	MR02381200509	RT/M Proxi CMC
73400329MR238174	MR2381-RL	MR02381200609	RT/L Proxi CMC
73400329MR238174	MR2381-RXL	MR02381200709	RT/XL Proxi CMC

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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:	36206
EMDN code:	Y06120601
Product model/version:	MBA141
Product:	Armis Ankle with Boa
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To provide support to the ankle.
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 2022-03-25

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329MBA1413Y	-	MBA141-XS	XS Armis Ankle with Boa
73400329MBA1413Y	-	MBA141-S	S Armis Ankle with Boa
73400329MBA1413Y	-	MBA141-M	M Armis Ankle with Boa
73400329MBA1413Y	-	MBA141-L	L Armis Ankle with Boa
73400329MBA1413Y	-	MBA141-XL	XL Armis Ankle with Boa
73400329MBA1413Y	-	MBA141-XXL	XXL Armis Ankle with Boa

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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:	36206
EMDN code:	Y06120601
Product model/version:	MBA140
Product:	Armis Ankle Light with Boa
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To provide support to the ankle.
Expiry date:	10 years from production date on LOT/batch code.

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Sollentuna 2022-03-25

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329MBA1403W	-	MBA140-XXS	XXS Armis Ankle Light with Boa
73400329MBA1403W	-	MBA140-XS	XS Armis Ankle Light with Boa
73400329MBA1403W	-	MBA140-S	S Armis Ankle Light with Boa
73400329MBA1403W	-	MBA140-M	M Armis Ankle Light with Boa
73400329MBA1403W	-	MBA140-L	L Armis Ankle Light with Boa
73400329MBA1403W	-	MBA140-XL	XL Armis Ankle Light with Boa

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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:	41459
EMDN code:	Y060613
Product model/version:	MR328
Product:	DYFEX FHP
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To support the wrist, hand, fingers and thumb in a resting position with inflatable bladders.
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
73400329MR328BW	-	MR00328100409	LT/S DYFEX FHP
73400329MR328BW	-	MR00328100509	LT/M DYFEX FHP
73400329MR328BW	-	MR00328100609	LT/L DYFEX FHP
73400329MR328BW	-	MR00328200409	RT/S DYFEX FHP
73400329MR328BW	-	MR00328200509	RT/M DYFEX FHP
73400329MR328BW	-	MR00328200609	RT/L DYFEX FHP

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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:	41465
EMDN code:	Y060621
Product model/version:	NEA940
Product:	Neatec ErixThree Neuro
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To support the shoulder both mechanical and proprioception as well as creating a posterior safe position of the shoulder. The additional straps can be used both for suspension of the shoulder joint as well as proprioceptive feedback.
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 2022-05-09

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329NEA9406L	-	NEA940-RT/XXS	RT/XXS Neatec Erix Three, Black
73400329NEA9406L	-	NEA940-RT/XS	RT/XS Neatec Erix Three, Black
73400329NEA9406L	-	NEA940-RT/S	RT/S Neatec Erix Three, Black
73400329NEA9406L	-	NEA940-RT/M	RT/M Neatec Erix Three, Black
73400329NEA9406L	-	NEA940-RT/L	RT/L Neatec Erix Three, Black
73400329NEA9406L	-	NEA940-RT/XL	RT/XL Neatec Erix Three, Black
73400329NEA9406L	-	NEA940-LT/XXS	LT/XXS Neatec Erix Three, Black
73400329NEA9406L	-	NEA940-LT/XS	LT/XS Neatec Erix Three, Black
73400329NEA9406L	-	NEA940-LT/S	LT/S Neatec Erix Three, Black
73400329NEA9406L	-	NEA940-LT/M	LT/M Neatec Erix Three, Black
73400329NEA9406L	-	NEA940-LT/L	LT/L Neatec Erix Three, Black
73400329NEA9406L	-	NEA940-LT/XL	LT/XL Neatec Erix Three, Black

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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:	41465
EMDN code:	Y060621
Product model/version:	MR960
Product:	Shoulder Brace erixtwo
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To support the shoulder both mechanical and proprioception as well as creating a posterior safe position of the shoulder. The pre applied straps can be used for additional joint compression.
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 2022-05-09

Lars Engstrand, QA

Basic UDI-DI	Art no short	Art no long	Description
73400329MR960CQ	-	MR00960100309	Vä/XS ErixTwo Axelortos singel
73400329MR960CQ	-	MR00960100409	Vä/S ErixTwo Axelortos singel
73400329MR960CQ	-	MR00960100509	Vä/M ErixTwo Axelortos singel
73400329MR960CQ	-	MR00960100609	Vä/L ErixTwo Axelortos singel
73400329MR960CQ	-	MR00960100709	Vä/XL ErixTwo Axelortos singel
73400329MR960CQ	-	MR00960200309	Hö/XS ErixTwo Axelortos singel
73400329MR960CQ	-	MR00960200409	Hö/S ErixTwo Axelortos singel
73400329MR960CQ	-	MR00960200509	Hö/M ErixTwo Axelortos singel
73400329MR960CQ	-	MR00960200609	Hö/L ErixTwo Axelortos singel
73400329MR960CQ	-	MR00960200709	Hö/XL ErixTwo Axelortos singel

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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:	43445
EMDN code:	Y060306
Product model/version:	EXT150
Product:	EXTO Inter
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To support the posture and provide moderate immobilization of the upper thoracic area.
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 2022-03-11

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329EXT150CG	-	EXT150-P	EXTO Inter, Petite
73400329EXT150CG	-	EXT150-S	EXTO Inter, Small
73400329EXT150CG	-	EXT150-L	EXTO Inter, Large

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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

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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:	MR2920
Product:	Manex Rheuma Pediatric
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	A light joint support for the wrist, applied over the wrist joint to provide light support, proprioception and light stability in volar flexion.
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 2022-03-28

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329MR29207E	MR2920-LXS	MR02920100309	LT/XS Manex Rheuma Pediatric
73400329MR29207E	MR2920-LS	MR02920100409	LT/S Manex Rheuma Pediatric
73400329MR29207E	MR2920-LM	MR02920100509	LT/M Manex Rheuma Pediatric
73400329MR29207E	MR2920-LL	MR02920100609	LT/L Manex Rheuma Pediatric
73400329MR29207E	MR2920-LXL	MR02920100709	LT/XL Manex Rheuma Pediatric
73400329MR29207E	MR2920-RXS	MR02920200309	RT/XS Manex Rheuma Pediatric
73400329MR29207E	MR2920-RS	MR02920200409	RT/S Manex Rheuma Pediatric
73400329MR29207E	MR2920-RM	MR02920200509	RT/M Manex Rheuma Pediatric
73400329MR29207E	MR2920-RL	MR02920200609	RT/L Manex Rheuma Pediatric
73400329MR29207E	MR2920-RXL	MR02920200709	RT/XL Manex Rheuma Pediatric

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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:	MR2338
Product:	Proxi Plus Thumb
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	A stable joint support for the thumb, applied over the thumb to provide support and mechanical stability to the UCL and RCL ligaments and proprioception.
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 2022-02-23

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329MR233873	MR2338-LXS	MR02338100309	LT/XS Proxi Plus Thumb, Black
73400329MR233873	MR2338-LS	MR02338100409	LT/S Proxi Plus Thumb, Black
73400329MR233873	MR2338-LM	MR02338100509	LT/M Proxi Plus Thumb, Black
73400329MR233873	MR2338-LL	MR02338100609	LT/L Proxi Plus Thumb, Black
73400329MR233873	MR2338-LXL	MR02338100709	LT/XL Proxi Plus Thumb, Black
73400329MR233873	MR2338-RXS	MR02338200309	RT/XS Proxi Plus Thumb, Black
73400329MR233873	MR2338-RS	MR02338200409	RT/S Proxi Plus Thumb, Black
73400329MR233873	MR2338-RM	MR02338200509	RT/M Proxi Plus Thumb, Black
73400329MR233873	MR2338-RL	MR02338200609	RT/L Proxi Plus Thumb, Black
73400329MR233873	MR2338-RXL	MR02338200709	RT/XL Proxi Plus Thumb, Black

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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:	41459
EMDN code:	Y060613
Product model/version:	E25
Product:	Resto Basic
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To support the wrist, hand, fingers and thumb in a functional position.
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 2022-03-28

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329E25P4	-	E25-LXS	LT XS RESTO Basic
73400329E25P4	-	E25-LS	LT S RESTO Basic
73400329E25P4	-	E25-LM	LT M RESTO Basic
73400329E25P4	-	E25-LL	LT L RESTO Basic
73400329E25P4	-	E25-RXS	RT XS RESTO Basic
73400329E25P4	-	E25-RS	RT S RESTO Basic
73400329E25P4	-	E25-RM	RT M RESTO Basic
73400329E25P4	-	E25-RL	RT L RESTO Basic

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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:	41057
EMDN code:	Y060680
Product model/version:	TON812
Product:	Finger Separation Strap for TONUS
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To separate the 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 2022-03-24

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329TON812EZ	-	TON812-U	Finger sep.Strap TONUS Univ

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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:	Y060603
Product model/version:	MR407
Product:	Neatec Tonus Fixed mit C-Luftblase
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To support and position the wrist, fingers and thumb in flexion during spasticity.
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 2022-05-09

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329MR407BT	-	MR407-SL	Neatec Tonus Fixed Standard
73400329MR407BT	-	MR407-SR	Neatec Tonus Fixed Standard
73400329MR407BT	-	MR407-XL	Neatec Tonus Fixed X-Lang
73400329MR407BT	-	MR407-XR	Neatec Tonus Fixed X-Lang

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Declaration of Conformity

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SRN number:	SE-MF-000007821
GMDN code:	41457
EMDN code:	Y060603
Product model/version:	MR405
Product:	Neatec Tonus Fixed mit RG-Luftblase
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To support and position the wrist, fingers and thumb in flexion during spasticity.
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 2022-05-09

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329MR405BP	-	MR405-PL	Neatec Tonus Fixed Pedi/Geratric
73400329MR405BP	-	MR405-PR	Neatec Tonus Fixed Pedi/Geratric
73400329MR405BP	-	MR405-SL	Neatec Tonus Fixed Standard
73400329MR405BP	-	MR405-SR	Neatec Tonus Fixed Standard
73400329MR405BP	-	MR405-XL	Neatec Tonus Fixed X-Lang
73400329MR405BP	-	MR405-XR	Neatec Tonus Fixed X-Lang

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:	Y060603
Product model/version:	MR403
Product:	Neatec Tonus Hand Roll
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To support the fingers to prevent pressure in the vola.
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 2022-03-25

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329MR403BK	-	MR403-L	Neatec Tonus Hand Roll
73400329MR403BK	-	MR403-R	Neatec Tonus Hand Roll

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SRN number:	SE-MF-000007821
GMDN code:	41457
EMDN code:	Y060603
Product model/version:	MR406
Product:	Neatec Tonus Rotation mit RG-Luftblase
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To support and position the wrist, fingers and thumb in flexion during spasticity.
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 2022-05-09

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329MR406BR	-	MR406-PL	Neatec Tonus Rotation Pedi/Geratric
73400329MR406BR	-	MR406-PR	Neatec Tonus Rotation Pedi/Geratric
73400329MR406BR	-	MR406-SL	Neatec Tonus Rotation Standard
73400329MR406BR	-	MR406-SR	Neatec Tonus Rotation Standard
73400329MR406BR	-	MR406-XL	Neatec Tonus Rotation X-Lang
73400329MR406BR	-	MR406-XR	Neatec Tonus Rotation X-Lang

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SRN number:	SE-MF-000007821
GMDN code:	41457
EMDN code:	Y060603
Product model/version:	MR2202
Product:	Ulnar Deviation
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	A joint support for the MCP to provide support to the joints in both flexion and ulnar drift passively.
Expiry date:	10 years from production date on LOT/batch code.

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Sollentuna 2022-03-09

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329MR220269	MR2202-LS	MR02202100409	LT/S Ulnar Deviation
73400329MR220269	MR2202-LM	MR02202100509	LT/M Ulnar Deviation
73400329MR220269	MR2202-LL	MR02202100609	LT/L Ulnar Deviation
73400329MR220269	MR2202-RS	MR02202200409	RT/S Ulnar Deviation
73400329MR220269	MR2202-RM	MR02202200509	RT/M Ulnar Deviation
73400329MR220269	MR2202-RL	MR02202200609	RT/L Ulnar Deviation

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SRN number:	SE-MF-000007821
GMDN code:	41459
EMDN code:	Y060613
Product model/version:	E28
Product:	Resto Dyfex
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To support the wrist, hand, fingers and thumb in a functional position for spasticity.
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 2024-12-06

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329E28PA	-	E28-LS	LT S RESTO DYFEX
73400329E28PA	-	E28-LM	LT M RESTO DYFEX
73400329E28PA	-	E28-LL	LT L RESTO DYFEX
73400329E28PA	-	E28-RS	RT S RESTO DYFEX
73400329E28PA	-	E28-RM	RT M RESTO DYFEX
73400329E28PA	-	E28-RL	RT L RESTO DYFEX