CE

REF

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:	-
EMDN code:	Y061280
Product model/version:	EU445280
Product:	Self Adhesive Loop 50 mm Black, 25 m
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To be used to secure straps.
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 2026-08-07

Lars Engstrand, QA

Basic UDI-DI	Art no short	Art no long	Description
73400329EU44528027	-	EU445280	Self Adhesive Loop 50 mm Black, 25 m

Doc. No	EU445280	Version:	1.0

CE

REF

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:	Y060680
Product model/version:	EU452900
Product:	NRX Strap Neptune Material
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To be used as a material for creating individual supports for joints, decided by the therapist that applies it individually.
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 2026-11-05

Lars Engstrand, QA

Basic UDI-DI	Art no short	Art no long	Description
73400329EU45290028	-	EU452900	NRX Strap Neptune Material

Doc. No	EU452900	Version:	1.0

CE

REF

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:	Y060680
Product model/version:	EU471100
Product:	Mesh Fabric/Self Adhesive Padding
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	Padding of splints or orthotic devices for the hand, back, knee or foot.
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 2026-11-05

Lars Engstrand, QA

Basic UDI-DI	Art no short	Art no long	Description
73400329EU471100ZC	-	EU471100	Mesh Fabric/Self Adhesive Padding

Doc. No	EU471100	Version:	1.0

CE

REF

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:	-
EMDN code:	Y061280
Product model/version:	EU445270
Product:	Hook Coin 20 mm Black, 5 m roll
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	Precut hook to be used to secure straps.

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 2026-05-21

Lars Engstrand, QA

Basic UDI-DI	Art no short	Art no long	Description
73400329EU44527024	-	EU445270	Hook Coin 20 mm Black, 5 m roll

Doc. No	EU445270	Version:	1.0

CE

REF

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:	-
EMDN code:	Y061280
Product model/version:	EU445271
Product:	Hook Coin 30 mm Black, 5 m roll
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	Precut hook to be used to secure straps.

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 2026-05-21

Lars Engstrand, QA

Basic UDI-DI	Art no short	Art no long	Description
73400329EU44527126	-	EU445271	Hook Coin 30 mm Black, 5 m roll

Doc. No	EU445271	Version:	1.0

CE

REF

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:	-
EMDN code:	Y061280
Product model/version:	EU445272
Product:	Hook Oval 25 x 45 mm, 5 m roll
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	Precut hook to be used to secure straps.

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 2026-05-21

Lars Engstrand, QA

Basic UDI-DI	Art no short	Art no long	Description
73400329EU44527228	-	EU445272	Hook Oval 25 x 45 mm, 5 m roll

Doc. No	EU445272	Version:	1.0

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:	Y060680
Product model/version:	EU451020, EU451030, EU451300
Product:	Ventus Fleece Edge
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	Used as lining and padding for orthotics.
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 2025-09-09

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329EU451020YP	-	EU451020	Ventus Fleece Edging tape 20mm, 5m
73400329EU451030YS	-	EU451030	Ventus Fleece Edging tape 30mm, 5m
73400329EU451300YY	-	EU451300	Ventus Fleece padding mtr 1 m

CE

REF

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:	Y060680
Product model/version:	EU457900
Product:	SRX Strap Mtr Navy Blue 58 x 100
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To be used as a light support for joints, decided by the therapist that applies it individually.
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 2026-02-17



Basic UDI-DI	Art no short	Art no long	Description
73400329EU4579003B	EU457900	EU457900	SRX Strap Mtr Navy Blue 58 x 100

Doc. No	EU454900	Version:	1.0

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:	Y061280
Product model/version:	EU445240, EU445250
Product:	Double X-Strap 40 mm, 50 mm x 10 m
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	Attach and close orthotics over complex shapes.
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 2025-11-13

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329EU445240ZQ	-	EU445240	Double X-Strap 40 mm x 10 m roll
73400329EU445250ZT	-	EU445250	Double X-Strap 50 mm x 10 m roll

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:	Y060680
Product model/version:	EU445260
Product:	NRX Doublesided hook standard/strong
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To close loop fabrics on top of each other to attach and close orthotic solutions.
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 2025-11-13

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329EU445260ZW	-	EU445260	NRX Doublesided hook standard/strong

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:	Y061280
Product model/version:	EU445201, EU445202, EU445203, EU445204, EU445205
Product:	Clips 20, 25, 30, 38 & 50 mm width
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	Integration and adaption of orthotics to seal the straping.
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 2025-11-07

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329EU445201ZE	-	EU445201	Clips 20 mm width x 10 pcs
73400329EU445202ZG	-	EU445202	Clips 25 mm width x 10 pcs
73400329EU445203ZJ	-	EU445203	Clips 30 mm width x 10 pcs
73400329EU445204ZL	-	EU445204	Clips 38 mm width x 10 pcs
73400329EU445205ZN	-	EU445205	Clips 50 mm width x 10 pcs

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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:	41457
EMDN code:	Y060606
Product model/version:	MR2707
Product:	Proxi TFCC Strap
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	A wrist support with thermoplastic for TFCC injuries.
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 2023-11-02

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329MR27077C	-	MR2707-S	S Proxi TFCC Strap
73400329MR27077C	-	MR2707-M	M Proxi TFCC Strap
73400329MR27077C	-	MR2707-L	L Proxi TFCC Strap

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:	Y060680
Product model/version:	EU445070, EU445070-01
Product:	Elastic Hook Strap 50mm
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To be used to secure the NRX Strap products.
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 2024-02-08

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329EU445070ZP	-	EU445070	Elastic Hook Strap 50mmx25 m
73400329EU445070ZP	-	EU445070-01	NRX Elastic Hook 50mm x 1 m

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:	Y060680
Product model/version:	EU490080
Product:	NRX Heat Tape Thermoplastic Kit
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To be used to make custom made orthotics.
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 2024-07-08

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329EU4900802H	-	EU490080	NRX Heat Tape Thermoplastic Kit

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:	Y060680
Product model/version:	EU490001
Product:	NRX Heat Activated Tape, Black
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To be used to make custom orthotics by joining textile materials without sewing.
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 2023-09-06

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329EU490001ZQ	-	EU490001	NRX Heat Activated Tape, Black

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:	Y060680
Product model/version:	EU490002
Product:	NRX Heat Activated Tape 35mm x10m
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To be used to make custom orthotics by joining textile materials without sewing.
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 2023-09-06

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329EU490002ZS	-	EU490002	NRX Heat Activated Tape 35mm x10m

Doc. no:	EU490090
Version:	5.0

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:	41456
EMDN code:	Y060603
Product model/version:	EU490090
Product:	NRX Loop Heat Tape Mtr 50mm x 5 m
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To be used to make custom orthotics by joining textile materials without sewing.
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 2024-01-03

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329EU4900902L	-	EU490090	NRX Loop Heat Tape Mtr 50mm x 5 m

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:	Y060699
Product model/version:	EU446601, EU446900, EU446603, EU446603-S, EU447602, EU447602-S
Product:	NRX® Strap Material 1/3 mm Black
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	Material for custom individual extremity splinting.
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 2023-12-19

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329EU4466012C	-	EU446601	NRX® Strap Material 1 mm Black
73400329EU4469002R	-	EU446900	NRX® Strap Material 1 mm Black
73400329EU4466032G	-	EU446603	NRX® Strap Material 3 mm Black
73400329EU4466032G	-	EU446603-S	NRX® Strap Material 3 mm Black
73400329EU4476022M	-	EU447602	NRX® Strap Double Mtr 3mm Black
73400329EU4476022M	-	EU447602-S	NRX® Strap Double Mtr 3mm Black

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:	Y060680
Product model/version:	EU456030, EU456080, EU456100
Product:	SRX Strap Como 5 m
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To be used as a light support for joints, decided by the therapist that applies it individually.
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 2023-12-13

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329EU456030ZV	-	EU456030	SRX Strap, Camo Grey, 30 mm x 5 m
73400329EU4560802F	-	EU456080	SRX Strap, Camo Grey, 80 mm x 5 m
73400329EU456100ZR	-	EU456100	SRX Strap, Camo Grey, 100 mm x 5 m

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:	NRX945
Product:	2-point Boa Fit System for ErixThree Neuro
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To support the shoulder 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 2022-05-31

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329NRX945GE	-	NRX945	ErixThree Neuro Boa 2-point system

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:	NRX946
Product:	3-point Boa Fit System for ErixThree Neuro
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To support the shoulder 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 2022-05-31



REF

Basic UDI-DI	Art no short	Art no long	Description
73400329NRX946GG	-	NRX946	ErixThree Neuro Boa 3-point system

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:	Y060680
Product model/version:	EU445060
Product:	NRX Hook Self Adhesive
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To be used to secure the NRX Strap products.
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 2022-05-11

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329EU445060ZL	-	EU445060	NRX Hook Self Adhesive

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:	Y060680
Product model/version:	EU445061
Product:	NRX Hook
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To be used to secure the NRX Strap products.
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 2022-05-11

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329EU445061ZN	-	EU445061	NRX Hook

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:	Y060680
Product model/version:	EU446001, EU446002, EU446003
Product:	Low profile pre-cut hook
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To be used to secure the NRX Strap products.
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 2022-04-12



Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329EU446001ZB	-	EU446001	Low profile pre-cut hook for 30mm strap
73400329EU446002ZD	-	EU446002	Low profile pre-cut hook for 50mm strap
73400329EU446003ZF	-	EU446003	Low profile pre-cut hook for 110mm strap

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:	Y060680
Product model/version:	EU446030, EU446050, EU446110
Product:	NRX strap 3.1m, Black
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To be used as a light support for joints, decided by the therapist that applies it individually.
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 2022-03-29

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329EU446030ZJ	-	EU446030	NRX Strap 30 mm x 3,1 meter
73400329EU446050ZQ	-	EU446050	NRX Strap 50 mm x 3,1 meter
73400329EU446110ZH	-	EU446110	NRX Strap 110 mm x 3,1 meter

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:	Y060680
Product model/version:	EU446210, EU446230, EU446250
Product:	NRX Strap Colors 3,1m, Royal Blue
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To be used as a light support for joints, decided by the therapist that applies it individually.
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 2022-03-29

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329EU446230ZU	-	EU446230	NRX Strap Colors 30 mm x 3,1 meter
73400329EU44625025	-	EU446250	NRX Strap Colors 50 mm x 3,1 meter
73400329EU446210ZN	-	EU446210	NRX-Strap Colors 110 mm x 3,1 meter

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:	Y060680
Product model/version:	EU447030, EU447050, EU447110, EU447300
Product:	NRX-Strap Double 3,1 m, Black
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To be used as a light support for joints, decided by the therapist that applies it individually.
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 2022-04-12

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329EU447030ZR	-	EU447030	NRX-Strap Double 30mm x 3,1 m
73400329EU44705022	-	EU447050	NRX-Strap Double 50mm x 3,1 m
73400329EU447110ZQ	-	EU447110	NRX-Strap Double 110mm x 3,1 m
73400329EU44730022	-	EU447300	NRX-Strap Double 300mm x 3,1 m

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:	Y060680
Product model/version:	EU449030, EU449050, EU449080, EU449110
Product:	NRX Plus Strap 3,1m, Black
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To be used as a light support for joints, decided by the therapist that applies it individually.
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 2022-04-12

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329EU4490302A	-	EU449030	NRX Plus Strap 30mm x 3,1m
73400329EU4490502G	-	EU449050	NRX Plus Strap 50mm x 3,1m
73400329EU4490802R	-	EU449080	NRX Plus Strap 80mm x 3,1m
73400329EU44911029	-	EU449110	NRX Plus Strap 110mm x 3,1m

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:	41053
EMDN code:	Y060615
Product model/version:	NRX1006
Product:	NRX Strap Kit Epicondylitis
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To be used as a support for epicondylitis.
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
73400329NRX1006FL	-	NRX1006	NRX Strap Kit Epicondylitis

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:	41053
EMDN code:	Y060680
Product model/version:	TFC104
Product:	Elbow Closure system with Boa
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To close the elbow part TFC105.
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 2022-05-13



REF

Basic UDI-DI	Art no short	Art no long	Description
73400329TFC1048F	-	TFC104	Boa Closure kit for TFCC Elbow

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:	41456
EMDN code:	Y060603
Product model/version:	EU448013, EU448014, EU448015
Product:	ARX Twin Strap
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	Light support to the finger or toe.
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 2022-05-11

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329EU44801323	-	EU445013	ARX Twin Bandage finger/toe 5p
73400329EU44801425	-	EU448014	ARX Twin Bandage for finger/toe 25p
73400329EU44801527	-	EU448015	ARX Twin Bandage for finger/toe 50p

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:	Y060680
Product model/version:	EU452030, EU452060, EU452120
Product:	NRX Strap Neptune 3,1m, Black
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To be used as a light support for joints, decided by the therapist that applies it individually.
Expiry date:	10 years from production date on LOT/batch code.

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Sollentuna 2022-04-12

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329EU452030YZ	-	EU452030	NRX Strap Neptune 30mmx3,1m, Black
73400329EU452060ZA	-	EU452060	NRX Strap Neptune 60mmx3,1m, Black
73400329EU45212OZ3	-	EU452120	NRX Strap Neptune 120mmx3,1m, Black

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:	Y060619
Product model/version:	NRX1002
Product:	NRX Strap Kit Supination Sling
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To be used as a support to assist supination or pronation.
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
73400329NRX1002FC	-	NRX1002	NRX Strap Kit Supination Sling, 1 set

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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:	41457
EMDN code:	Y060606
Product model/version:	NRX1004
Product:	NRX Strap Kit Thumb Abduction
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To be used as a support for the thumb.
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
73400329NRX1004FG	-	NRX1004	NRX Strap Kit Thumb Abduction, 1 set

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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:	41435
EMDN code:	Y061203
Product model/version:	NRX1003
Product:	NRX Strap Kit Hallus Valgus
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To be used as a support for hallux valgus.
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
73400329NRX1003FE	-	NRX1003	NRX Strap Kit Hallux Valgus, 1 set

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:	41435
EMDN code:	Y061203
Product model/version:	NRX1001
Product:	NRX Strap Kit Hammertoes
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To be used as a support for hammertoes.
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
73400329NRX1001FA	-	NRX1001	NRX Strap Kit Hammertoes, 1 set

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:	36228
EMDN code:	Y061215
Product model/version:	NRX1005
Product:	NRX Strap Kit Hip Rotation
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To be used as a support for the hip to provide external rotation.
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
73400329NRX1005FJ	-	NRX1005	NRX Strap Kit Hip Rotation, 1 set

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:	41456
EMDN code:	Y060603
Product model/version:	NRX1007
Product:	NRX Strap Kit Twin-bandage 15 mm
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	To be used as a support for fingers or toes.
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
73400329NRX1007FN	-	NRX1007-06	NRX Strap Kit Twin-bandage 15 mm 6p
73400329NRX1007FN	-	NRX1007-30	NRX Strap Kit Twin-bandage 15 mm 30p
73400329NRX1007FN	-	NRX1007-60	NRX Strap Kit Twin-bandage 15 mm 60p

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:	Y060699
Product model/version:	EU490101, EU490101-S, EU490103, EU490103-S, EU490105, EU490105-S
Product:	Neoprene 1/3/5 mm OP Loop/Black Nylon
Risk class according to annex VIII:	Class 1
Conformity route:	Annex IV (class I product)
Intended purpose:	Material for custom individual extremity splinting.
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 2023-12-19

Lars Engstrand, QA

REF

Basic UDI-DI	Art no short	Art no long	Description
73400329EU490101ZV	-	EU490101	Neoprene 1 mm OP Loop/Black Nylon
73400329EU490101ZV	-	EU490101-S	Neoprene 1 mm OP Loop/Black Nylon
73400329EU49010324	-	EU490103	Neoprene 3 mm OP Loop/Black Nylon
73400329EU49010324	-	EU490103-S	Neoprene 3 mm OP Loop/Black Nylon
73400329EU49010528	-	EU490105	Neoprene 5 mm OP Loop/Black Nylon
73400329EU49010528	-	EU490105-S	Neoprene 5 mm OP Loop/Black Nylon