



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
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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.

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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
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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.

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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
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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.

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Sollentuna 2025-09-09


Lars Engstrand, QA

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



Declaration of Conformity

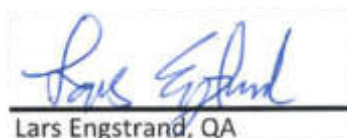
Manufacturer: Mediroyal Nordic AB
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SRN number: SE-MF-000007821
GMDN code: 41457
EMDN code: Y060680
Product model/version: EU457900
Product: SRX Strap Mtr Navy Blue 58 x 100
Risk class according to annex VIII: Class 1
Conformity route: Annex IV (class 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.

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Sollentuna 2026-02-17



Lars Engstrand, QA

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
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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

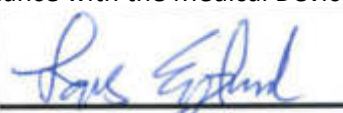
Conformity route: Annex IV (class I product)

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

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



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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

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



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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

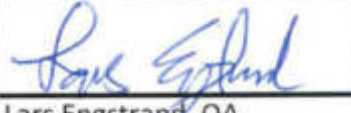
Conformity route: Annex IV (class I product)

Intended purpose: Integration and adaption of orthotics to seal the strapping.

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

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Sollentuna 2025-11-07


Lars Engstrand, QA

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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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

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



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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.

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Sollentuna 2024-02-08


Lars Engstrand, QA

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



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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.

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Sollentuna 2024-07-08


Lars Engstrand, QA

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



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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.

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Sollentuna 2023-09-06


Lars Engstrand, QA

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



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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.

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Sollentuna 2023-09-06


Lars Engstrand, QA

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



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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.

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Sollentuna 2024-01-03


Lars Engstrand, QA

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



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 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.

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Sollentuna 2023-12-19



 Lars Engstrand, QA

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



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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.

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Sollentuna 2023-12-13




 Lars Engstrand, QA

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



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 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.

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Sollentuna 2022-05-31




 Lars Engstrand, QA

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



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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


Lars Engstrand, QA

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



Declaration of Conformity

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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.

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Sollentuna 2022-05-11


Lars Engstrand, QA

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



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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.

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Sollentuna 2022-05-11


Lars Engstrand, QA

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



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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.

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Sollentuna 2022-04-12


Lars Engstrand, QA

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



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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.

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Sollentuna 2022-03-29


Lars Engstrand, QA

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



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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.

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Sollentuna 2022-03-29


Lars Engstrand, QA

Basic UDI-DI	Art no short	Art no long	Description
73400329EU446230ZU	-	EU446230	NRX Strap Colors 30 mm x 3,1 meter
73400329EU446250Z5	-	EU446250	NRX Strap Colors 50 mm x 3,1 meter
73400329EU446210ZN	-	EU446210	NRX-Strap Colors 110 mm x 3,1 meter



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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

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



Declaration of Conformity

Manufacturer: Mediroyal Nordic AB
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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.

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Sollentuna 2022-04-12


Lars Engstrand, QA

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



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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

Basic UDI-DI	Art no short	Art no long	Description
73400329NRX1006FL	-	NRX1006	NRX Strap Kit Epicondylitis



Declaration of Conformity

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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


Lars Engstrand, QA

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



Declaration of Conformity

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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

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



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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

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
73400329EU452120Z3	-	EU452120	NRX Strap Neptune 120mmx3,1m, Black



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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

Basic UDI-DI	Art no short	Art no long	Description
73400329NRX1002FC	-	NRX1002	NRX Strap Kit Supination Sling, 1 set



Declaration of Conformity

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 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

Basic UDI-DI	Art no short	Art no long	Description
73400329NRX1004FG	-	NRX1004	NRX Strap Kit Thumb Abduction, 1 set



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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

Basic UDI-DI	Art no short	Art no long	Description
73400329NRX1003FE	-	NRX1003	NRX Strap Kit Hallux Valgus, 1 set



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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

Basic UDI-DI	Art no short	Art no long	Description
73400329NRX1001FA	-	NRX1001	NRX Strap Kit Hammertoes, 1 set



Declaration of Conformity

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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.

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

Basic UDI-DI	Art no short	Art no long	Description
73400329NRX1005FJ	-	NRX1005	NRX Strap Kit Hip Rotation, 1 set



Declaration of Conformity

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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.

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

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



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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

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