

Konformitätserklärung | Declaration of Conformity

Hiermit erklären wir |
Hereby we

NOVAFON – Elektromedizinische Geräte GmbH

Daimlerstr. 13, D-71384 Weinstadt

SRN: DE-MF-000006137

in alleiniger Verantwortung, dass die genannten Produkte den einschlägigen Anforderungen der Medizinprodukte-Verordnung 2017/745/EU (gem. Anhang IV) entsprechen.

declare in our own responsibility that the products listed have undergone a procedure of conformity assessment according to annex IV of EU Medical Device Directive 2017/745/EU. The products do fulfil the relevant requirements thereof.

Zubehör für NOVAFON Schallwellengeräte |

Accessories for NOVAFON Vibration Sound Wave Devices

(Klasse I gemäß Regel 1 Anhang VIII 2017/745/EU Medizinprodukte-Verordnung |
Class I acc. to rule 1 of annex VIII of 2017/745/EU Medical Device Directive

Zweckbestimmung

Alle im folgenden gelisteten Zubehöre ermöglichen oder erleichtern die Anwendung der NOVAFON Schallwellengeräte und deren Zweckbestimmung.

Intended Use

All accessories subsequently listed allow or facilitate the use and application of NOVAFON vibration sound wave devices and thus follow the same intended use.

Diese Erklärung ist gültig bis | This declaration is valid until 2024-05-10

Weinstadt, 2023-05-11



rechtsgültige Unterschrift | legally binding signature
Alexander Kauffmann, Geschäftsführer | CEO

Design: Magnetverbindung | Magnetic connector

| Color Basic UDI Artikelbezeichnung Accessory name | Farbe | Weiß White | | Grau Gray | | Schwarz black | |
|---|-------|--------------------|---------------|------------------------|---------------|--------------------|---------------|
| | | Art.-Nr. Ref. | UDI-DI | Art.- Nr. Ref. | UDI-DI | Art.-Nr. Ref. | UDI-DI |
| 426020379MagnetaufsatzVT Magnetau Magnetic attachment fsatz | | 7001 | 4260203791235 | 7002 | 4260203791693 | 7012 | 4260203792379 |
| 426020379RehaF9 Reha-Set Rehabilitation set Bestehend aus Consisting of: Igelaufsatz Pin attachment Kegelaufsatz Cone attachment Telleraufsatz XL Disk attachment XL | | 7016 | 4260203791181 | 7036 | 4260203791655 | 7021 | 4260203792409 |
| | | 7013 | 4260203791150 | 7033 | 4260203791662 | 7018 | 4260203791303 |
| | | 7014 | 4260203791174 | 7034 | 4260203791686 | 7019 | 4260203792386 |
| | | 7015 | 4260203791167 | 7035 | 4260203791679 | 7020 | 4260203792393 |
| | | | | | | | |
| 426020379SensiN5 Sensi-Roller Set Sensory Roller Set Bestehend aus Consisting of: Sensi-Rolle weich roll soft Sensi-Rolle mittel roll medium Sensi-Rolle hart roll hard Halteclip clip Adapter Sensi-Roller adapter | | 7017 | 4260203791709 | 7037 | 4260203791716 | 7052 | 4260203792454 |
| | | 5019 | 4260203791563 | 5019 | 4260203791563 | 5019 | 4260203791563 |
| | | 5020 | 4260203791570 | 5020 | 4260203791570 | 5020 | 4260203791570 |
| | | 5021 | 4260203791587 | 5021 | 4260203791587 | 5021 | 4260203791587 |
| | | 7023 | 4260203791730 | 7022 | 4260203791747 | 7053 | 4260203792461 |
| | | 7007 | 4260203791198 | 7097 | 4260203791860 | 7054 | 4260203791396 |
| | | | | | | | |
| 426020379Physio3J Physio-Set Physio Set Bestehend aus Consisting of: Faszien-Ball fascia ball Faszien-Gabel fascia fork Faszien-Keil fascia wedge | | 7044 | 4260203791952 | 7040 | 4260203791914 | 7048 | 4260203792416 |
| | | 7045 | 4260203791969 | 7041 | 4260203791921 | 7049 | 4260203792423 |
| | | 7046 | 4260203791976 | 7042 | 4260203791938 | 7050 | 4260203792430 |
| | | 7047 | 4260203791983 | 7043 | 4260203791945 | 7051 | 4260203792447 |
| | | | | | | | |
| 426020379HandleQP Verlängerungsgriff Extension Handle | | 7038 | 4260203791877 | 7039 | 4260203791341 | 7008 | 4260203792362 |
| 426020379ModularJF Modular-Set Modular Set Bestehend aus Consisting of: Ovalaufsatz Oval attachment Grip-Modul Grip module Noppen-Modul Nub module Trigger-Modul Trigger module | | 7028 | 4260203792478 | 7055 | 4260203792522 | 7057 | 4260203792546 |
| | | 7029 | 4260203792485 | 7056 | 4260203792539 | 7058 | 4260203792553 |
| | | 7030 | 4260203792492 | 7030 | 4260203792492 | 7030 | 4260203792492 |
| | | 7031 | 4260203792508 | 7031 | 4260203792508 | 7031 | 4260203792508 |
| | | 7032 | 4260203792515 | 7032 | 4260203792515 | 7032 | 4260203792515 |

| 426020379HandleQP Verlängerungsgriff Extension Handle | Art.-Nr. Ref. | UDI-DI |
|---|-----------------|---------------|
| Weiß White | 7038 | 4260203791877 |
| Grau Gray | 7039 | 4260203791341 |
| Schwarz Black | 7008 | 4260203792362 |
| Grün Green | 7100-014 | 4260203792874 |
| Blau Blue | 7100-016 | 4260203792881 |
| Lila Purple | 7100-018 | 4260203792898 |
| Gelb Yellow | 7100-020 | 4260203792904 |
| Orange | 7100-022 | 4260203792911 |
| Rosé | 7100-024 | 4260203792928 |

Design: Schraubgewinde | screw connector

| Artikelbezeichnung Accessory name | Art.-Nr. Ref. | Basis-UDI Basic UDI |
|---|------------------------|----------------------------------|
| Telleraufsatz disk attachment Classic/ power Pro | 5093 5092 | 4260203790115 4260203790122 |
| Kugelaufsatz ball attachment | 5091 | 4260203790139 |
| Adapter adapter | 5007 | 4260203792010 |
| Magnetaufsatz vergoldet Magnetic attachment (gold plated), also compact head | 0001 | 4260203790108 |
| Magnetaufsatz verchromt Magnetic attachment (chrome plated), also compact head | 0002 | 4260203790498 |

| Angewandte gemeinsame Spezifikationen und harmonisierte Normen Common specifications and harmonized standards applied | | |
|--|--|---|
| Nummer Number | Titel Title | Harmonisiert seit Harmonized as of |
| EN ISO 10993-12:2021 | Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021) | 05/01/2022 |
| EN ISO 13485:2016, EN ISO 13485:2016/A11:2021, EN ISO 13485:2016/AC:2018 | Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) | 17/05/2022 |
| EN ISO 14971:2019, EN ISO 14971:2019/A11:2021 | Medical devices - Application of risk management to medical devices (ISO 14971:2019) | 17/05/2022 |
| EN ISO 15223-1:2021 | Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021) | 05/01/2022 |
| EN ISO 17664-1:2021 | Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices (ISO 17664-1:2021) | 05/01/2022 |