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Konformitätserklärung | Declaration of Conformity

NOVAFON Schallwellengerät | NOVAFON Vibration Sound Wave Devices

Bezeichnung | Description	Art.-Nr. | Ref.	Farben | colour	Typ | Type	UDI-DI
novafon one+ (logo)	R11384710	Schwarz/ blau | black/blue	SK4	4260203793802
novafon one (logo)	R11384707	Weiß / blau | white / blue	SK3	4260203794113
novafon one+ Intraoral-Senso	R11404631	Schwarz/ blau | black/blue	SK4	4260203794502
novafon one Intraoral-Senso	R11404633	Weiß / blau | white / blue	SK3	4260203794519

BASIC UDI: 426020379NOVAFONSKGS

Zweckbestimmung

Geräte und Zubehör von NOVAFON sind für die Linderung von Schmerzen und die Förderung der Muskelentspannung vorgesehen um Symptome in folgenden Bereichen zu lindern:

(1) Akute Schmerzen des muskoskelettales System

(2) Chronische Schmerzen des muskoskelettalen Systems

(3) Neuro-Rehabilitation (Sensomotorik)

(4) Stimm- und Schlucktherapie

Intended Use

NOVAFON devices and accessories are designed to relieve pains and aid in relaxation of muscles to alleviate symptoms of:

(1) Temporary and transient pain of the musculoskeletal system

(2) Chronical pain of the musculoskeletal system

(3) Neuro-rehabilitation (senso motorics)

(4) Voice and swallowing therapy

Klasse IIa gemäß Regel 9 Anhang VIII 2017/745/EU Medizinprodukte-Verordnung

Folgende Benannte Stelle ist am Konformitätsbewertungsverfahren nach Anhang IX Kapitel I und III der Verordnung 2017/745/EU beteiligt

Class IIa acc. to rule 9 of annex VIII of 2017/745/EU Medical Device Directive

The following notified body took part in the conformity assessment procedure in accordance with annex IX chapters I and III of the regulation 2017/745/EU

TÜV SÜD Product Service GmbH, Ridlerstr. 65, D - 80339 München

Kennnummer | ID 0123 Zertifikatsnummer | Certificate No: G10 036048 0007 Rev. 01

Diese Erklärung ist gültig bis | This declaration is valid until 2028-10-22.

Weinstadt, 2026-10-23

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

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Hiermit erklären wir | Hereby we

NOVAFON - Elektromedizinische Geräte GmbH

Daimlerstr. 13, D-71384 Weinstadt

SRN: DE-MF-000006137

in alleiniger Verantwortung, dass die hier genannten Produkte den einschlägigen Anforderungen der folgenden Verordnungen und Richtlinien entsprechen.

declare in our own responsibility that the products listed herein fulfil the relevant requirements of the following regulations and directives.

Medizinprodukte-Verordnung 2017/745/EU
sowie
2011/65/EU mit 2011/65/EU ROHS Richtlinie
2014/30/EU EMV-Richtlinie
2023/1542/EU Batterieverordnung
2025/40/EU Verpackungsverordnung (PPWR)

Medical Device Regulation 2017/745/EU
In addition
2011/65/EU incl. 2011/65/EU ROHS directive
2014/30/EU EMC Directive
2023/1542/EU Battery Regulation
2025/40/EU packaging and packaging waste Regulation (PPWR)

Nur für novafon one+ (logo)
2014/53/EU Funkrichtlinie (RED)

Only for novafon one+ (logo)
2014/53/EU Radio Equipment Directive (RED)

Angewandte gemeinsame Spezifikationen und harmonisierte Normen | Common specifications and harmonized standards applied

Nummer | Number	Titel | Title	Harmonisiert seit | Harmonized as of
2017/745/EU		
EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)	OJ L 1 - 05/01/2022
EN ISO 10993-18:2020, EN ISO 10993-18:2020/A1:2023	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)	OJ L, 2024/815 - 08/03/2024
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)	OJ L 1 - 05/01/2022
EN ISO 14971:2019, EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)	OJ L 138 - 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)	OJ L 1 - 05/01/2022
EN ISO 17664-2:2023	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices (ISO 17664-2:2021)	OJ L, 2024/815 - 08/03/2024
2014/53/EU		
ETSI EN 300 328 V2.2.2	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band; Harmonised Standard for access to radio spectrum	OJ L 34 - 06/02/2020

ETSI EN 301 489-1 V2.2.3	Electro-Magnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for Electro-Magnetic Compatibility, also DIN EN 301489-1:2020-06	OJ L 2022/2191, 10/11/2022
ETSI EN 301 489-17 V3.3.1	Electro-Magnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband and Wideband Data Transmission Systems; Harmonised Standard for Electro-Magnetic Compatibility	OJ L, 2025/893 15/05/2025

Spare parts for commercial sale			
Name, Description	Article No	Color	GTIN/ UDI-DI
Telleraufsatz one | schwarz || Disc attachment one | black	7092-007	black	4260203793475
Kugelaufsatz one | schwarz || Ball attachment one | black	7091-007	black	4260203793499
Ladekabel (magnetisch), Netzteil Typ F (EU) | schwarz || Charging cable (magn.), Charger Type F (EU) | black	70607062-007	black	4260203793697
Telleraufsatz one | weiß || Disc attachment one | white	7092-040	white	4260203793468
Kugelaufsatz one | weiß || Ball attachment one | white	7091-040	white	4260203793482
Ladekabel USB-C, Netzteil Typ F (EU) | weiß ||Charging cable (USB-A to USB-C.), Charger Type F (EU) | white	70817082-040	white	4260203793789
Kugelstab one || Pellet Head one	7006-009	blue	4260203793604
Spatelaufsatz one || Tongue Depressor one	7003-009	blue	4260203793611
Löffelaufsatz one || Spoon Attachment one	7005-009	blue	4260203793628
Pfeilaufsatz one || Arrow Head one	7004-009	blue	4260203793635
Olivenroller one || Olive Roller one	7024-009	blue	4260203793642
Sensolöffel one || Sensory Spoon one	7025-009	blue	4260203793659
Kugelstab XL one || Pellet Head XL one	7026-009	blue	4260203793666
Trainingslöffel one || Training Spoon one	7027-009	blue	4260203793673
Adapter one | blau || Adaptor one | blue	7007-009	blue	4260203793680
Adapter one | transluzent || Adaptor one | translucent	7007-046	translucent	4260203794328
Senso-Duo one | weich || soft	7115-043	translucent, light blue	4260203794182
Senso-Duo one | mittel || medium	7115-044	translucent, medium blue	4260203794199

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Spare parts for commercial sale			
Name, Description	Article No	Color	GTIN/ UDI-DI
Senso-Duo one| hart || hard	7115-045	translucent, dark blue	4260203794205
Senso-Guide one | weich || soft	7116-043	translucent, light blue	4260203794212
Senso-Guide one | mittel || medium	7116-044	translucent, medium blue	4260203794229
Senso-Guide one | hart || hard	7116-045	translucent, dark blue	4260203794236
Senso-Loop one | weich || soft	7117-043	translucent, light blue	4260203794243
Senso-Loop one | mittel || medium	7117-044	translucent, medium blue	4260203794250
Senso-Loop one | hart || hard	7117-045	translucent, dark blue	4260203794267

Akkus können auf Anfrage durch den Hersteller getauscht werden

Batteries can be changed by the manufacturer upon request