REMED®
Comfort and health for Your life!

Production & Distribution
of orthopaedic supports & rehabilitation goods

75 Karuny str., Dnipro, Ukraine 49000
e-mail: info@remed.ua, web: remed.ua

EC - DECLARATION OF CONFORMITY

№ DC-CE from 2021-05-26
Orthopedic supports Class I (Rule 1) according to Medical Devices Regulation (EU) 2017/745 (MDR)

CE

Manufacturer:	PRIVATE ENTERPRISE "REMED", Reg.№37363941
Registration address:	75 Karuny str., Dnipro, Ukraine 49000
Production address:	53 Bazhova str., Dnipro, Ukraine 49000
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EC-Representative:	S-SPORT Ltd
Registration address:	15/2 Geo Milev Str., Sofia, Bulgaria 1111

We herewith declare under sole responsibility that the Class I medical devices listed below are in conformity with general safety and performance requirements which apply Annex I of the EU MDR. All supporting documentations are retained under the premises of the manufacturer.
This declaration is made in accordance with annex IV EU MDR and is valid for and undetermined period of time. PE REMED hereby declare that the equipment specified below conforms to MDR 2017/745.

No.	Item / device number	Product name	Size	Brand	Country of origin	GMDNS code / ISO 9999 code	GMN (Basic UDI-DI)
1	R1101	SOFT FIXATION CERVICAL COLLAR (SCHANZ COLLAR BRACE)	S, M, L	Remed	Ukraine	10938/ 060312	018323R1101RQ
2	R1102	CHILD CERVICAL COLLAR (SCHANZ COLLAR BRACE)	S, M, L	Remed	Ukraine	10938/ 060312	018323R1102RS
3	R1103	CERVICAL COLLAR WITH RIGID PANEL (SCHANZ COLLAR BRACE)	S, M, L	Remed	Ukraine	10938/ 060312	018323R1103RU
4	R2101	LIGHT FIXATION POSTURE BRACE ELASTIC	S, M	Remed	Ukraine	13858/ 060315	018323R2101RX
5	R2201	CHILD POSTURE SUPPORT ELASTIC	S, M, L	Remed	Ukraine	13858/ 060315	018323R2201S4
6	R2202	POSTURE SUPPORT MEDIUM FIXATION	S, M, L, XL	Remed	Ukraine	13858/ 060315	018323R2202S6
7	R2204	POSTURE SUPPORT MEDIUM FIXATION	S, M, L	Remed	Ukraine	13858/ 060315	018323R2204SA
8	R2301	HARD FIXATION CORSET BRACE (RECLINATOR)	S/I-II, M/I-II, L/I-II, XL/I-II, XXL/I-II	Remed	Ukraine	11024/ 060315	018323R2301S9
9	R2303	CLAVICULAR BRACE HARD FIXATION (DELBE'S RING)	Universal size	Remed	Ukraine	13858/ 060315	018323R2303SD
10	R3101	ANTI-RADICULITIS BELT	M,L	Remed	Ukraine	13858/	018323R3101S6

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11	R3201	SACRO LUMBAR SUPPORT WITH RENAL PADS	M,L,XL	Remed	Ukraine	13858/ 060315	018323R3201SB
12	R3202	AEROPRENE ORTHOPEDIC SUPPORT WITH STAYS	M,L,XL	Remed	Ukraine	13858/ 060315	018323R3202SD
13	R3205	BACK SUPPORT WITH STAYS	S,M,L,XL, XXL, XXXL	Remed	Ukraine	13858/ 060315	018323R3205SK
14	R3302	SACROLUMBAL MEDICAL SUPPORT WITH 4 STAYS	S,M,L,XL, XXL	Remed	Ukraine	11024/ 060315	018323R3302SJ
15	R4102	MATERNITY BELT PRE- AND POSTNATAL ELASTIC	S,M,L,XL	Remed	Ukraine	13858/ 060303	018323R4102SF
16	R4103	MEDICAL SUPPORT ELASTIC	S,M,L,XL, XXL, XXXL	Remed	Ukraine	13858/ 060303	018323R4103SH
17	R4104	MATERNITY SUPPORT	S,M,L,XL	Remed	Ukraine	13858/ 060303	018323R4104SK
18	R4117	UNIVERSAL SUPPORT	M,L,XL	Remed	Ukraine	13858/ 060306	018323R4117SU
19	R4204	SACRO LUMBAR SUPPORT WITH ADDITIONAL FIXATION AND REMOVABLE STAYS	M,L,XL	Remed	Ukraine	11024/ 060315	018323R4204SQ
20	R5202	UMBILICAL HERNIA SUPPORT	S,M,L,XL	Remed	Ukraine	13858/ 060306	018323R5202ST
21	R5205	HERNIA SUPPORT DOUBLE-SIDED	S,M,L	Remed	Ukraine	13858/ 060306	018323R5205SZ
22	R6101	KNEE JOINT SUPPORT ELASTIC KNITTED	S,M,L,XL	Remed	Ukraine	13858/ 061209	018323R6101ST
23	R6102	KNEE JOINT SUPPORT ADJUSTABLE	Universal size	Remed	Ukraine	13858/ 061209	018323R6102SV
24	R6105	KNEE JOINT SUPPORT ELASTIC	S,M,L,XL	Remed	Ukraine	13858/ 061209	018323R6105T3
25	R6201	KNEE JOINT SUPPORT ADJUSTABLE WITH SPIRAL STAYS	M, L, XL	Remed	Ukraine	13858/ 061209	018323R6201SY
26	R6202	KNEE JOINT SUPPORT WITH SPIRAL STAYS	S,M,L,XL	Remed	Ukraine	13858/ 061209	018323R6202T2
27	R6301	KNEE IMMOBILIZER (THE TUTOR) ADJUSTABLE	S,M,L	Remed	Ukraine	12099/ 061209	018323R6301T5
28	R6302	KNEE JOINT SUPPORT WITH POLYCENTRIC HINGES	M,L,XL	Remed	Ukraine	12837/ 061209	018323R6302T7
29	R7103	SHIN SUPPORT ADJUSTABLE	Universal size	Remed	Ukraine	13858/ 061206	018323R7103T6
30	R7105	ANKLE SUPPORT ELASTIC KNITTED REINFORCED	S,M,L,XL	Remed	Ukraine	13858/ 061206	018323R7105TA
31	R7106	ANKLE SUPPORT ELASTIC KNITTED	S,M,L,XL	Remed	Ukraine	13858/ 061206	018323R7106TC
32	R7201	DROP FOOT SYNDROME ANKLE SUPPORT	Universal size	Remed	Ukraine	13858/ 061218	018323R7201T7

33	R7202	ANKLE SUPPORT WITH ADDITIONAL FIXATION	S,M,L	Remed	Ukraine	13858/ 061215	018323R7202T9
34	R7203	HALLUX VALGUS NIGHT SUPPORT WITH RIB	M,L	Remed	Ukraine	13858/ 061215	018323R7203TB
35	R7204	ANKLE IMMOBILIZER (DEROTATION BOOT)	Universal size	Remed	Ukraine	12094/ 061215	018323R7204TD
36	R8101	WRIST WRAP FACILITATED	Universal size	Remed	Ukraine	13858/ 060609	018323R8101T9
37	R8102	WRIST SUPPORT ELASTIC KNITTED	S,M,L,XL	Remed	Ukraine	13858/ 060609	018323R8102TB
38	R8103	WRIST WRAP ELASTIC	Universal size	Remed	Ukraine	13858/ 060609	018323R8103TD
39	R8104	WRIST SUPPORT ELASTIC	S,M,L,XL	Remed	Ukraine	13858/ 060609	018323R8104TF
40	R8203	WRIST IMMOBILIZER	Universal size	Remed	Ukraine	12102/ 060609	018323R8203TJ
41	R8204	WRIST SUPPORT ADJUSTABLE	Universal size	Remed	Ukraine	13858/ 060609	018323R8204TL
42	R8301	WRIST SPLINT	M,L	Remed	Ukraine	12102/ 060609	018323R8301TK
43	R8301S	WRIST SPLINT SHORT	M,L	Remed	Ukraine	12102/ 060609	018323R8301SJJ
44	R8303	WRIST SPLINT WITH THUMB FIXATION	M,L	Remed	Ukraine	12102/ 060609	018323R8303TP
45	R8304	WRIST WRAP WITH THUMB FIXATION	M,L	Remed	Ukraine	12102/ 060609	018323R8304TR
46	R9102	ELBOW SUPPORT ELASTIC KNITTED	S,M,L,XL	Remed	Ukraine	13858/ 060615	018323R9102TJ
47	R9103	ARM SLING	S,M,L	Remed	Ukraine	13858/ 060619	018323R9103TL
48	R9104	ELBOW SUPPORT ELASTIC KNITTED REINFORCED	S,M,L,XL	Remed	Ukraine	13858/ 060615	018323R9104TN
49	R9109	ELBOW SUPPORT ELASTIC	S,M,L,XL	Remed	Ukraine	13858/ 060615	018323R9109TY
50	R9201	SHOULDER WRAP FIXATIVE (DESAULT'S BANDAGE)	S,M,L	Remed	Ukraine	13858/ 060619	018323R9201TM
51	R9202	ARM SUPPORT ABDUCTION CUSHION	M,L	Remed	Ukraine	13858/ 060619	018323R9202TP
52	R9202/10	ARM SUPPORT ABDUCTION CUSHION/10^{O}	M,L	Remed	Ukraine	13858/ 060619	018323R92021088
53	R9203	ELBOW SUPPORT WITH ADDITIONAL FIXATION	S,M,L,XL	Remed	Ukraine	13858/ 060619	018323R9203TR
54	R9205	ELBOW SUPPORT	M,L	Remed	Ukraine	13858/ 060619	018323R9205TV
55	R035U	ELASTIC BANDAGE (MEDIUM TENSILITY) 80MM	L=1м, 1.5м, 2м, 2.5м, 3м, 5м.	Remed	Ukraine	10279/ -	018323R035UUG

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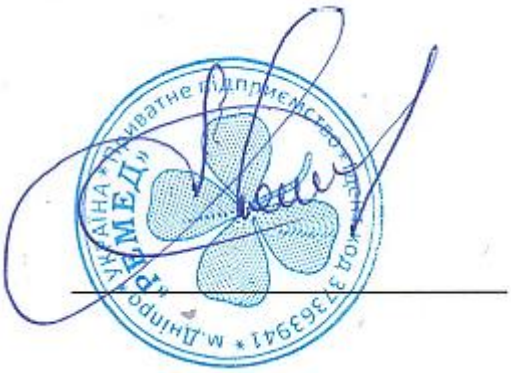
Medical Device Regulation

General applicable:
Medical Device Regulation: REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

The standards we conform: All applicable harmonized standards.

Expire date of the Declaration: 2024-11-29
Place, Date of Issue: 2021-11-24

Position of authorized person and signature/stamp

Oleksii Kanivets (CEO)