



Declaration of Conformity Certificate

Name of the manufacturer:

RESTORATIVE CARE OF AMERICA INCORPORATED (RCAI)

Address:

12221 33RD STREET NORTH
ST. PETERSBURG, FL 33716-1841 U.S.A.

We ***Restorative Care of America Incorporated (RCAI)*** declare and ensure with sole responsibility, that the below mentioned Medical Device(s) meet the provisions of Council Directive 93/42/EEC (Medical Device Regulation) which apply to them. The obligations laid down in Annex VII excluding section 5 for "Class I" products placed on the market.

NOTIFIED MEDICAL DEVICE & UMDNS DESCRIPTION

ORTHOSIS, ARM UMDNS CODE 17-872, RISK CLASS 1, CAT. CODE 11, REGISTRATION # DE/CA09/0170/2916
18ECO, 24ECO, 28ECO, 34ECO, 38ECO, 415-HEP, 48ES, 53HFB, 54HFB-OS, 58EPOP, 630-NES, 631-SXNES, 640-TEB, 650-HNES, 680-ESNES, 68BAB, 710-AS, 711-CS, 74APOP, 74S/P-ATT, 84RAPOP, 88UAB
ORTHOSIS, BACK UMDNS CODE 17-909, RISK CLASS 1, CAT. CODE 11, REGISTRATION # DE/CA09/0170/104A1
1460-SXFTLS, 1460TLS, 450LSO, 450-SXFLSO, 451-CF-LSO, 453-LSO, 455-HEO, 45LSO, 460SA, 460-SXFTLS, 460TLS, 461-CF-TLS, 463TLS, 463TLS-S, 46TLS, 56GB, 700-RB, 701-RB, 702-AB
ORTHOSIS, HIP UMDNS CODE 17-930, RISK CLASS 1, CAT. CODE 11, REGISTRATION # DE/CA09/0170/2917
16HR, 26AB, 665-PHDH, 66BHS, 66HNG, 66HS, 76ARA, 76BHAO, 76GRD, 76HAO, 76HAO-LITE, 76HNG, 76PSB, 86BHAOHD, 86GRDHD, 86HAOHD, 86HNGHD, 96HD-BHAO, 96HD-GRD, 96HD-HNG
ORTHOSIS, KNEE UMDNS CODE 17-874, RISK CLASS 1, CAT. CODE 11, REGISTRATION # DE/CA09/0170/2918
17KCO, 23KCO, 27KCO, 33KCO, 35KCO, 35SKCO, 37KCO, 41CPM, 420-BKI, 42KI, 42SPKI, 523-PTS, 530-NKS, 531-WKS, 540-SKS, 545-LJKB, 546-HLJKB, 550-HKB, 560-WKB, 561-WKB, 570-NKA, 571-DXWNKO, 572-PCDXWKB, 575-OAWKB, 577-POPDXXWKB, 57FKPOP, 65SWKCO, 670-SR-RKPOP, 67RKFPPOP, 73HDP, 770-UPOP, 77POP, 83DLHDP, 870-ULB, 87PDULB, 87ULB, 93DXHDDL, 97DLPOP, 97-DXDLPOP
ORTHOSIS, FOOT/ANKLE UMDNS CODE 17-873, RISK CLASS 1, CAT. CODE 11, REGISTRATION # DE/CA09/0170/106A1
00-BFO, 01MP, 02MP, 03CX, 03-KCX, 06MP, 07MP, 09MP, 100-USAB, 10MP, 11DFMP, 12AA, 12MP, 12SB, 13CX, 13-KCX, 19MP, 20AA, 20IES, 20MP, 21MP, 220-SPFS, 222-DPFS, 22PFNS, 400-EAS, 401-AFAS, 402-GFAS, 40AFO, 40FF-AFO, 415-HEP, 416-DPK, 50LS-AFO, 60RAFO, 70AAFO, 78TA, 80SI, 90SAFO, AM
ORTHOSIS, WRIST UMDNS CODE 17-911, RISK CLASS 1, CAT. CODE 11, REGISTRATION # DE/CA09/0170/2919
14OS, 15DHO, 15RDHO, 15SDH, 25PHO, 29RHO, 29SHL, 300-ACH, 30CHK, 31SCK, 320-AGH, 32GHK, 32GHO, 36FS-NTRHO, 36NTRHO, 390-ARH, 39SRH, 43DBS, 445ATT, 445-WDO, 44DCT, 49BRH, 500-CMCS, 502-NETS, 504-PWTS, 510-UTS, 515-NWW, 520-UWTS, 590-STY, 590-WES, 591-WFS, 592-WETS, 593-UWS, 59FEO, 64FBFXO, 71FFXO, 72WFXO,

We explicitly designate MDSS GmbH, Schiffgraben 41, 30175 Hannover, Germany to act as our sole Authorized Representative in the European Union for the above indicated



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Dean Josloff

Signature

March 1st, 2021

Date

Dean Josloff, Executive VP
Printed Name / Title



RESTORATIVE CARE OF AMERICA
12221 33RD STREET NORTH
ST PETERSBURG, FL 33716
PHONE (727) 573-1595 FAX (800) 545-7938

July 26, 2023

Neatec GmbH
Dieselstrasse 6
89231 Neu-Ulm, Germany

To Whom it May Concern,

Restorative Care of America Incorporated (RCAI) is a reputed manufacturer and supplier of manufacture of superior quality orthopedic and rehabilitative orthoses and registered under the laws of U.S.A and having its principal place of business at 12221 33RD street North, St. Petersburg, FL, USA, phone number +1 (727) 573-1595.

Restorative Care of America Incorporated (RCAI), declares that neaTec GmbH, located at Dieselstrasse 6, 89231 Neu-Ulm, Germany is our Distributor for our products in Germany.

All products are in conformity with the essential requirements and provisions concerning Medical Products Regulations 2017/745 MDR.

We hereby authorize neaTec GmbH to do all necessary registration of our products, within the German market.

This authorization letter is valid for one year and will be expired on July 26th 2024.

Sincerely,

Heidi Rodriguez

Heidi Rodriguez
Controller