



**Declaration of Conformity Certificate**  
According to MDR 2017/745 Annex IV

**Name of the manufacturer:** RESTORATIVE CARE OF AMERICA INC (RCAI)  
**Address:** 12221 33RD STREET NORTH  
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**Authorized Representative:** MDSS GmbH  
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**We Restorative Care of America Inc (RCAI) declare and ensure, with sole responsibility, that the below-mentioned Medical Device(s) meet the provisions of the Medical Device Regulation (EU) 2017/745 (MDR) which apply to them.**

**The devices covered by the present declaration are in conformity with the MDR.**

| PRODUCT NAME                                        | PRODUCT CODE | BASIC UDI-DI (GMN) | GMDN  |
|-----------------------------------------------------|--------------|--------------------|-------|
| MPO 2000 Accessory Kit / Replacement Liner          | 01AK-C       | 064229901AK-C42    | 41435 |
| MPO 2000 Accessory Kit / Replacement Liner          | 01AK-I       | 064229901AK-I4E    | 41435 |
| MPO 2000 Accessory Kit / Replacement Liner          | 01AK-L       | 064229901AK-L4L    | 41435 |
| MPO 2000 Accessory Kit / Replacement Liner          | 01AK-M       | 064229901AK-M4N    | 41435 |
| MPO 2000 Accessory Kit / Replacement Liner          | 01AK-S       | 064229901AK-S52    | 41435 |
| MPO 2000 Accessory Kit / Replacement Liner          | 01AK-T       | 064229901AK-T54    | 41435 |
| MPO 2000 Accessory Kit / Replacement Liner          | 01AK-XL      | 064229901AK-XLYW   | 41435 |
| MPO 2000 Accessory Kit / Replacement Liner          | 01AK-XXL     | 064229901AK-XXL2N  | 41435 |
| MPO 2000 Accessory Kit / Replacement Liner          | 01AK-Y       | 064229901AK-Y5E    | 41435 |
| MPO 2000 Orthosis                                   | 01MP-C       | 064229901MP-CKY    | 41435 |
| MPO 2000 Orthosis                                   | 01MP-I       | 064229901MP-ILC    | 41435 |
| MPO 2000 Orthosis                                   | 01MP-L       | 064229901MP-L7Z    | 41435 |
| MPO 2000 Orthosis                                   | 01MP-M       | 064229901MP-M83    | 41435 |
| MPO 2000 Orthosis                                   | 01MP-S       | 064229901MP-S8F    | 41435 |
| MPO 2000 Orthosis                                   | 01MP-T       | 064229901MP-T8H    | 41435 |
| MPO 2000 Orthosis                                   | 01MP-XL      | 064229901MP-XL68   | 41435 |
| MPO 2000 Orthosis                                   | 01MP-XXL     | 064229901MP-XXL99  | 41435 |
| MPO 2000 Orthosis                                   | 01MP-Y       | 064229901MP-Y8T    | 41435 |
| MPO 2000 Active with Ambulatory Attachment Orthosis | 02MP-L       | 064229902MP-L8C    | 41435 |
| MPO 2000 Active with Ambulatory Attachment Orthosis | 02MP-M       | 064229902MP-M8E    | 41435 |
| MPO 2000 Active with Ambulatory Attachment Orthosis | 02MP-S       | 064229902MP-S8S    | 41435 |
| MPO 2000 Active with Ambulatory Attachment Orthosis | 02MP-XL      | 064229902MP-XL6M   | 41435 |
| MPO 7000 Orthosis                                   | 07GMP-L      | 064229907GMP-L7B   | 41435 |
| MPO 7000 Orthosis                                   | 07GMP-M      | 064229907GMP-M7D   | 41435 |
| MPO 7000 Orthosis                                   | 07GMP-S      | 064229907GMP-S7R   | 41435 |
| MPO 7000 Orthosis                                   | 07GMP-XL     | 064229907GMP-XL9U  | 41435 |
| Ambulatory Attachment                               | 09AA-A       | 064229909AA-S68    | 41435 |
| Ambulatory Attachment                               | 09AA-S       | 064229909AA-S68    | 41435 |



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| MPO - W/ Ambulatory Attachment Orthosis         | 09MP-L       | 064229909MP-LAR     | 41435 |
| MPO - W/ Ambulatory Attachment Orthosis         | 09MP-M       | 064229909MP-MAT     | 41435 |
| MPO - W/ Ambulatory Attachment Orthosis         | 09MP-S       | 064229909MP-SB7     | 41435 |
| MPO - W/ Ambulatory Attachment Orthosis         | 09MP-XL      | 064229909MP-XL9G    | 41435 |
| Multi Podus Accessory Kit / Replacement Liner   | 10AK-C       | 064229910AK-C44     | 41435 |
| Multi Podus Accessory Kit / Replacement Liner   | 10AK-L       | 064229910AK-L4N     | 41435 |
| Multi Podus Accessory Kit / Replacement Liner   | 10AK-M       | 064229910AK-M4Q     | 41435 |
| Multi Podus Accessory Kit / Replacement Liner   | 10AK-S       | 064229910AK-S54     | 41435 |
| Multi Podus Accessory Kit / Replacement Liner   | 10AK-T       | 064229910AK-T56     | 41435 |
| Multi Podus Accessory Kit / Replacement Liner   | 10AK-XL      | 064229910AK-XLZ2    | 41435 |
| Multi Podus Accessory Kit / Replacement Liner   | 10AK-XXL     | 064229910AK-XXL2Q   | 41435 |
| 10MPO Accessory Kit                             | 10AK-Y       | 064229910AK-Y5G     | 41435 |
| Multi Podus® Orthosis                           | 10MP-C       | 064229910MP-C7H     | 41435 |
| Multi Podus® Orthosis                           | 10MP-I       | 064229910MP-I7V     | 41435 |
| Multi Podus® Orthosis                           | 10MP-L       | 064229910MP-L83     | 41435 |
| Multi Podus® Orthosis                           | 10MP-M       | 064229910MP-M85     | 41435 |
| Multi Podus® Orthosis                           | 10MP-S       | 064229910MP-S8H     | 41435 |
| Multi Podus® Orthosis                           | 10MP-T       | 064229910MP-T8K     | 41435 |
| Multi Podus® Orthosis                           | 10MP-XL      | 064229910MP-XL6C    | 41435 |
| Multi Podus® Orthosis                           | 10MP-XXL     | 064229910MP-XXL9B   | 41435 |
| Multi Podus® Orthosis                           | 10MP-Y       | 064229910MP-Y8V     | 41435 |
| Dorsi-Flexion Multipodus Orthowick Brace        | 11DFMP-L     | 064229911DFMP-L4C   | 41435 |
| Dorsi-Flexion Multipodus Orthowick Brace        | 11DFMP-M     | 064229911DFMP-M4E   | 41435 |
| Dorsi-Flexion Multipodus Orthowick Brace        | 11DFMP-P     | 064229911DFMP-P4L   | 41435 |
| Dorsi-Flexion Multipodus Orthowick Brace        | 11DFMP-S     | 064229911DFMP-S4S   | 41435 |
| Dorsi-Flexion Multipodus Orthowick Brace        | 11DFMP-XL    | 064229911DFMP-XLAM  | 41435 |
| Dorsi-Flexion Multipodus Orthowick Brace        | 11DFMP-Y     | 064229911DFMP-Y56   | 41435 |
| MPO Burn Unit Brace                             | 12MP-C       | 064229912MP-C87     | 41435 |
| MPO Burn Unit Brace                             | 12MP-I       | 064229912MP-I8K     | 41435 |
| MPO Burn Unit Brace                             | 12MP-L       | 064229912MP-L8R     | 41435 |
| MPO Burn Unit Brace                             | 12MP-M       | 064229912MP-M8T     | 41435 |
| MPO Burn Unit Brace                             | 12MP-S       | 064229912MP-S97     | 41435 |
| MPO Burn Unit Brace                             | 12MP-T       | 064229912MP-T99     | 41435 |
| MPO Burn Unit Brace                             | 12MP-XL      | 064229912MP-XL76    | 41435 |
| MPO Burn Unit Brace                             | 12MP-Y       | 064229912MP-Y9K     | 41435 |
| Opponent Hand Accessory Kit / Replacement Liner | 14AK-L-L     | 064229914AK-L-LWX   | 41459 |
| Opponent Hand Accessory Kit / Replacement Liner | 14AK-L-R     | 064229914AK-L-RXB   | 41459 |
| Opponent Hand Accessory Kit / Replacement Liner | 14AK-M-L     | 064229914AK-M-LX4   | 41459 |
| Opponent Hand Accessory Kit / Replacement Liner | 14AK-M-R     | 064229914AK-M-RXG   | 41459 |
| Opponent Hand Accessory Kit / Replacement Liner | 14AK-S-L     | 064229914AK-S-LY2   | 41459 |
| Opponent Hand Accessory Kit / Replacement Liner | 14AK-S-R     | 064229914AK-S-RYE   | 41459 |
| Opponent Hand Orthosis                          | 14OS-L-L     | 064229914OS-L-L7G   | 41459 |
| Opponent Hand Orthosis                          | 14OS-L-R     | 064229914OS-L-R7U   | 41459 |
| Opponent Hand Orthosis                          | 14OS-M-L     | 064229914OS-M-L7M   | 41459 |
| Opponent Hand Orthosis                          | 14OS-M-R     | 064229914OS-M-R7Z   | 41459 |
| Opponent Hand Orthosis                          | 14OS-S-L     | 064229914OS-S-L8K   | 41459 |
| Opponent Hand Orthosis                          | 14OS-S-R     | 064229914OS-S-R8X   | 41459 |
| Dorsal Hand Brace Without Finger Separators     | 15DHO-ES-L   | 064229915DHO-ES-LFY | 41459 |
| Dorsal Hand Brace Without Finger Separators     | 15DHO-ES-R   | 064229915DHO-ES-RGC | 41459 |
| Dorsal Hand Brace Without Finger Separators     | 15DHO-L-L    | 064229915DHO-L-L7T  | 41459 |
| Dorsal Hand Brace Without Finger Separators     | 15DHO-L-R    | 064229915DHO-L-R87  | 41459 |
| Dorsal Hand Brace Without Finger Separators     | 15DHO-M-L    | 064229915DHO-M-L7Y  | 41459 |
| Dorsal Hand Brace Without Finger Separators     | 15DHO-M-R    | 064229915DHO-M-R8C  | 41459 |
| Dorsal Hand Brace Without Finger Separators     | 15DHO-S-L    | 064229915DHO-S-L8W  | 41459 |



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| Dorsal Hand Brace Without Finger Separators           | 15DHO-S-R    | 064229915DHO-S-R9A  | 41459 |
| Dorsal Hand Brace Without Finger Separators           | 15DHO-XL-L   | 064229915DHO-XL-LK2 | 41459 |
| Dorsal Hand Brace Without Finger Separators           | 15DHO-XL-R   | 064229915DHO-XL-RKE | 41459 |
| Dorsal Resting Hand w/FS Accessory Kit                | 15SAK-L-L    | 064229915SAK-L-LBK  | 41459 |
| Dorsal Resting Hand w/FS Accessory Kit                | 15SAK-L-R    | 064229915SAK-L-RBX  | 41459 |
| Dorsal Resting Hand w/FS Accessory Kit                | 15SAK-M-L    | 064229915SAK-M-LBQ  | 41459 |
| Dorsal Resting Hand w/FS Accessory Kit                | 15SAK-M-R    | 064229915SAK-M-RC4  | 41459 |
| Dorsal Resting Hand w/FS Accessory Kit                | 15SAK-S-L    | 064229915SAK-S-LCN  | 41459 |
| Dorsal Resting Hand w/FS Accessory Kit                | 15SAK-S-R    | 064229915SAK-S-RD2  | 41459 |
| Dorsal Resting Hand w/FS Accessory Kit                | 15SAK-XL-L   | 064229915SAK-XL-LNL | 41459 |
| Dorsal Resting Hand w/FS Accessory Kit                | 15SAK-XL-R   | 064229915SAK-XL-RNY | 41459 |
| Dorsal Hand Brace With Finger Separators              | 15SDH-L-L    | 064229915SDH-L-LBR  | 41459 |
| Dorsal Hand Brace With Finger Separators              | 15SDH-L-R    | 064229915SDH-L-RC5  | 41459 |
| Dorsal Hand Brace With Finger Separators              | 15SDH-M-L    | 064229915SDH-M-LBW  | 41459 |
| Dorsal Hand Brace With Finger Separators              | 15SDH-M-R    | 064229915SDH-M-RCA  | 41459 |
| Dorsal Hand Brace With Finger Separators              | 15SDH-S-L    | 064229915SDH-S-LCU  | 41459 |
| Dorsal Hand Brace With Finger Separators              | 15SDH-S-R    | 064229915SDH-S-RD8  | 41459 |
| Dorsal Hand Brace With Finger Separators              | 15SDH-XL-L   | 064229915SDH-XL-LNY | 41459 |
| Dorsal Hand Brace With Finger Separators              | 15SDH-XL-R   | 064229915SDH-XL-RPC | 41459 |
| Phase II Multi Podus System Orthosis with Kodel Liner | 20MP-A-A     | 064229920MP-A-AZL   | 41435 |
| Phase II Multi Podus System Orthosis with Kodel Liner | 20MP-A-L     | 064229920MP-A-L2D   | 41435 |
| Phase II Multi Podus System Orthosis with Kodel Liner | 20MP-A-P     | 064229920MP-A-P2M   | 41435 |
| Phase II Multi Podus System Orthosis with Kodel Liner | 20MP-A-S     | 064229920MP-A-S2T   | 41435 |
| Phase II Multi Podus System Orthosis with Kodel Liner | 20MP-A-XL    | 064229920MP-A-XL5N  | 41435 |
| Phase II Multi Podus System Orthosis with Kodel Liner | 20MP-A-Y     | 064229920MP-A-Y37   | 41435 |
| Plantar Fasciitis Night Splint / Brace                | 22PFNS-C     | 064229922PFNS-CAG   | 41435 |
| Plantar Fasciitis Night Splint / Brace                | 22PFNS-ES    | 064229922PFNS-ESHY  | 41435 |
| Plantar Fasciitis Night Splint / Brace                | 22PFNS-L     | 064229922PFNS-LB2   | 41435 |
| Plantar Fasciitis Night Splint / Brace                | 22PFNS-M     | 064229922PFNS-MB4   | 41435 |
| Plantar Fasciitis Night Splint / Brace                | 22PFNS-S     | 064229922PFNS-SBG   | 41435 |
| Plantar Fasciitis Night Splint / Brace                | 22PFNS-T     | 064229922PFNS-TBJ   | 41435 |
| Plantar Fasciitis Night Splint / Brace                | 22PFNS-XL    | 064229922PFNS-XLKB  | 41435 |
| Plantar Fasciitis Night Splint / Brace                | 22PFNS-Y     | 064229922PFNS-YBU   | 41435 |
| Abduction Bar Brace                                   | 26AB-A-N     | 064229926AB-A-NTW   | 36228 |
| Abduction Bar Brace                                   | 26AB-A-W     | 064229926AB-A-WUG   | 36228 |
| Abduction Bar Brace                                   | 26AB-P-N     | 064229926AB-P-NW9   | 36228 |
| Abduction Bar Brace                                   | 26AB-P-W     | 064229926AB-P-WWT   | 36228 |
| Abduction Bar Brace                                   | 26AB-P-xN    | 064229926AB-P-Xn34  | 36228 |
| Resting Hand Orthosis Without Finger Separators       | 29RHO-C-L    | 064229929RHO-C-LGX  | 41459 |
| Resting Hand Orthosis Without Finger Separators       | 29RHO-C-R    | 064229929RHO-C-RHB  | 41459 |
| Resting Hand Orthosis Without Finger Separators       | 29RHO-ES-L   | 064229929RHO-ES-LU3 | 41459 |
| Resting Hand Orthosis Without Finger Separators       | 29RHO-ES-R   | 064229929RHO-ES-RUF | 41459 |
| Resting Hand Orthosis Without Finger Separators       | 29RHO-I-L    | 064229929RHO-I-LHV  | 41459 |
| Resting Hand Orthosis Without Finger Separators       | 29RHO-I-R    | 064229929RHO-I-RJ9  | 41459 |
| Resting Hand Orthosis Without Finger Separators       | 29RHO-L-L    | 064229929RHO-L-LJC  | 41459 |
| Resting Hand Orthosis Without Finger Separators       | 29RHO-L-R    | 064229929RHO-L-RJQ  | 41459 |
| Resting Hand Orthosis Without Finger Separators       | 29RHO-M-L    | 064229929RHO-M-LJH  | 41459 |
| Resting Hand Orthosis Without Finger Separators       | 29RHO-M-R    | 064229929RHO-M-RJV  | 41459 |
| Resting Hand Orthosis Without Finger Separators       | 29RHO-S-L    | 064229929RHO-S-LKF  | 41459 |
| Resting Hand Orthosis Without Finger Separators       | 29RHO-S-R    | 064229929RHO-S-RKT  | 41459 |
| Resting Hand Orthosis Without Finger Separators       | 29RHO-T-L    | 064229929RHO-T-LKL  | 41459 |
| Resting Hand Orthosis Without Finger Separators       | 29RHO-T-R    | 064229929RHO-T-RKY  | 41459 |
| Resting Hand Orthosis Without Finger Separators       | 29RHO-XL-L   | 064229929RHO-XL-LX5 | 41459 |
| Resting Hand Orthosis Without Finger Separators       | 29RHO-XL-R   | 064229929RHO-XL-RXH | 41459 |



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| Resting Hand Orthosis Without Finger Separators       | 29RHO-Y-L    | 064229929RHO-Y-LLD  | 41459 |
| Resting Hand Orthosis Without Finger Separators       | 29RHO-Y-R    | 064229929RHO-Y-RLR  | 41459 |
| Contour Hand Orthosis                                 | 30CHK-ES-L   | 064229930CHK-ES-LBY | 41459 |
| Contour Hand Orthosis                                 | 30CHK-ES-R   | 064229930CHK-ES-RCC | 41459 |
| Contour Hand Orthosis                                 | 30CHK-L-L    | 064229930CHK-L-L4D  | 41459 |
| Contour Hand Orthosis                                 | 30CHK-L-R    | 064229930CHK-L-R4R  | 41459 |
| Contour Hand Orthosis                                 | 30CHK-M-L    | 064229930CHK-M-L4J  | 41459 |
| Contour Hand Orthosis                                 | 30CHK-M-R    | 064229930CHK-M-R4W  | 41459 |
| Contour Hand Orthosis                                 | 30CHK-S-L    | 064229930CHK-S-L5G  | 41459 |
| Contour Hand Orthosis                                 | 30CHK-S-R    | 064229930CHK-S-R5U  | 41459 |
| Contour Hand s/FS Accessory Kit / Replacement Liner   | 31AK-L-L     | 064229931AK-L-LWJ   | 41457 |
| Contour Hand s/FS Accessory Kit / Replacement Liner   | 31AK-L-R     | 064229931AK-L-RWW   | 41457 |
| Contour Hand s/FS Accessory Kit / Replacement Liner   | 31AK-M-L     | 064229931AK-M-LWP   | 41457 |
| Contour Hand s/FS Accessory Kit / Replacement Liner   | 31AK-M-R     | 064229931AK-M-RX3   | 41457 |
| Contour Hand s/FS Accessory Kit / Replacement Liner   | 31AK-S-L     | 064229931AK-S-LXM   | 41457 |
| Contour Hand s/FS Accessory Kit / Replacement Liner   | 31AK-S-R     | 064229931AK-S-RXZ   | 41457 |
| Contour Hand Orthosis w/Finger Separators             | 31SCK-L-L    | 064229931SCK-L-LBF  | 41457 |
| Contour Hand Orthosis w/Finger Separators             | 31SCK-L-R    | 064229931SCK-L-RBT  | 41457 |
| Contour Hand Orthosis w/Finger Separators             | 31SCK-M-L    | 064229931SCK-M-LBL  | 41457 |
| Contour Hand Orthosis w/Finger Separators             | 31SCK-M-R    | 064229931SCK-M-RBY  | 41457 |
| Contour Hand Orthosis w/Finger Separators             | 31SCK-S-L    | 064229931SCK-S-LCJ  | 41457 |
| Contour Hand Orthosis w/Finger Separators             | 31SCK-S-R    | 064229931SCK-S-RCW  | 41457 |
| Geriatric Hand w/FS Accessory Kit / Replacement Liner | 32AK-ES-L    | 064229932AK-ES-LZS  | 41459 |
| Geriatric Hand w/FS Accessory Kit / Replacement Liner | 32AK-ES-R    | 064229932AK-ES-R29  | 41459 |
| Geriatric Hand w/FS Accessory Kit / Replacement Liner | 32AK-L-L     | 064229932AK-L-LX3   | 41459 |
| Geriatric Hand w/FS Accessory Kit / Replacement Liner | 32AK-L-R     | 064229932AK-L-RXF   | 41459 |
| Geriatric Hand w/FS Accessory Kit / Replacement Liner | 32AK-M-L     | 064229932AK-M-LX8   | 41459 |
| Geriatric Hand w/FS Accessory Kit / Replacement Liner | 32AK-M-R     | 064229932AK-M-RXL   | 41459 |
| Geriatric Hand w/FS Accessory Kit / Replacement Liner | 32AK-S-L     | 064229932AK-S-LY6   | 41459 |
| Geriatric Hand w/FS Accessory Kit / Replacement Liner | 32AK-S-R     | 064229932AK-S-RYJ   | 41459 |
| Geriatric Hand w/FS Accessory Kit / Replacement Liner | 32AK-XL-L    | 064229932AK-XL-L4X  | 41459 |
| Geriatric Hand w/FS Accessory Kit / Replacement Liner | 32AK-XL-R    | 064229932AK-XL-R5B  | 41459 |
| Geriatric Hand Brace with Separator                   | 32GHK-L-L    | 064229932GHK-L-L7P  | 41459 |
| Geriatric Hand Brace with Separator                   | 32GHK-L-R    | 064229932GHK-L-R83  | 41459 |
| Geriatric Hand Brace with Separator                   | 32GHK-M-L    | 064229932GHK-M-L7U  | 41459 |
| Geriatric Hand Brace with Separator                   | 32GHK-M-R    | 064229932GHK-M-R88  | 41459 |
| Geriatric Hand Brace with Separator                   | 32GHK-S-L    | 064229932GHK-S-L8S  | 41459 |
| Geriatric Hand Brace with Separator                   | 32GHK-S-R    | 064229932GHK-S-R96  | 41459 |
| Geriatric Hand Brace with Separator                   | 32GHK-XL-L   | 064229932GHK-XL-LJU | 41459 |
| Geriatric Hand Brace with Separator                   | 32GHK-XL-R   | 064229932GHK-XL-RK8 | 41459 |
| Respond ROM Knee Orthosis                             | 37KCO-ES     | 064229937KCO-ES89   | 41065 |
| Respond ROM Knee Orthosis                             | 37KCO-L      | 064229937KCO-L7X    | 41065 |
| Respond ROM Knee Orthosis                             | 37KCO-M      | 064229937KCO-M7Z    | 41065 |
| Respond ROM Knee Orthosis                             | 37KCO-S      | 064229937KCO-S8D    | 41065 |
| Respond ROM Elbow Orthosis                            | 38ECO-L      | 064229938ECO-L6A    | 41053 |
| Respond ROM Elbow Orthosis                            | 38ECO-M      | 064229938ECO-M6C    | 41053 |
| Respond ROM Elbow Orthosis                            | 38ECO-S      | 064229938ECO-S6Q    | 41053 |
| Resting Hand w/FS Accessory Kit / Replacement Liner   | 39SAK-L-L    | 064229939SAK-L-LFD  | 41459 |
| Resting Hand w/FS Accessory Kit / Replacement Liner   | 39SAK-L-R    | 064229939SAK-L-RFR  | 41459 |
| Resting Hand w/FS Accessory Kit / Replacement Liner   | 39SAK-M-L    | 064229939SAK-M-LFJ  | 41459 |
| Resting Hand w/FS Accessory Kit / Replacement Liner   | 39SAK-M-R    | 064229939SAK-M-RFW  | 41459 |
| Resting Hand w/FS Accessory Kit / Replacement Liner   | 39SAK-S-L    | 064229939SAK-S-LGG  | 41459 |
| Resting Hand w/FS Accessory Kit / Replacement Liner   | 39SAK-S-R    | 064229939SAK-S-RGU  | 41459 |
| Resting Hand w/FS Accessory Kit / Replacement Liner   | 39SAK-XL-L   | 064229939SAK-XL-LTA | 41459 |





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| Resting Hand w/FS Accessory Kit / Replacement Liner | 39SAK-XL-R   | 064229939SAK-XL-RTN  | 41459 |
| Resting Hand Orthosis With Finger Separators        | 39SRH-L-L    | 064229939SRH-L-LM9   | 41459 |
| Resting Hand Orthosis With Finger Separators        | 39SRH-L-R    | 064229939SRH-L-RMM   | 41459 |
| Resting Hand Orthosis With Finger Separators        | 39SRH-M-L    | 064229939SRH-M-LME   | 41459 |
| Resting Hand Orthosis With Finger Separators        | 39SRH-M-R    | 064229939SRH-M-RMS   | 41459 |
| Resting Hand Orthosis With Finger Separators        | 39SRH-S-L    | 064229939SRH-S-LNC   | 41459 |
| Resting Hand Orthosis With Finger Separators        | 39SRH-S-R    | 064229939SRH-S-RNQ   | 41459 |
| Resting Hand Orthosis With Finger Separators        | 39SRH-XL-L   | 064229939SRH-XL-L37  | 41459 |
| Resting Hand Orthosis With Finger Separators        | 39SRH-XL-R   | 064229939SRH-XL-R3K  | 41459 |
| Dorsal Carpal Tunnel Brace                          | 44DCT-ES-L   | 064229944DCT-ES-LHC  | 41459 |
| Dorsal Carpal Tunnel Brace                          | 44DCT-ES-R   | 064229944DCT-ES-RHQ  | 41459 |
| Dorsal Carpal Tunnel Brace                          | 44DCT-L-L    | 064229944DCT-L-L93   | 41459 |
| Dorsal Carpal Tunnel Brace                          | 44DCT-L-R    | 064229944DCT-L-R9F   | 41459 |
| Dorsal Carpal Tunnel Brace                          | 44DCT-M-L    | 064229944DCT-M-L98   | 41459 |
| Dorsal Carpal Tunnel Brace                          | 44DCT-M-R    | 064229944DCT-M-R9L   | 41459 |
| Dorsal Carpal Tunnel Brace                          | 44DCT-S-L    | 064229944DCT-S-LA6   | 41459 |
| Dorsal Carpal Tunnel Brace                          | 44DCT-S-R    | 064229944DCT-S-RAJ   | 41459 |
| Dorsal Carpal Tunnel Brace                          | 44DCT-XL-L   | 064229944DCT-XL-LLE  | 41459 |
| Dorsal Carpal Tunnel Brace                          | 44DCT-XL-R   | 064229944DCT-XL-RLS  | 41459 |
| Burn Resting Hand Accessory Kit / Replacement Liner | 49BAK-C-L    | 064229949BAK-C-L5N   | 41459 |
| Burn Resting Hand Accessory Kit / Replacement Liner | 49BAK-C-R    | 064229949BAK-C-R62   | 41459 |
| Burn Resting Hand Accessory Kit / Replacement Liner | 49BAK-ES-L   | 064229949BAK-ES-LF2  | 41459 |
| Burn Resting Hand Accessory Kit / Replacement Liner | 49BAK-ES-R   | 064229949BAK-ES-RFE  | 41459 |
| Burn Resting Hand Accessory Kit / Replacement Liner | 49BAK-L-L    | 064229949BAK-L-L73   | 41459 |
| Burn Resting Hand Accessory Kit / Replacement Liner | 49BAK-L-R    | 064229949BAK-L-R7F   | 41459 |
| Burn Resting Hand Accessory Kit / Replacement Liner | 49BAK-M-L    | 064229949BAK-M-L78   | 41459 |
| Burn Resting Hand Accessory Kit / Replacement Liner | 49BAK-M-R    | 064229949BAK-M-R7L   | 41459 |
| Burn Resting Hand Accessory Kit / Replacement Liner | 49BAK-S-L    | 064229949BAK-S-L86   | 41459 |
| Burn Resting Hand Accessory Kit / Replacement Liner | 49BAK-S-R    | 064229949BAK-S-R8J   | 41459 |
| Burn Resting Hand Accessory Kit / Replacement Liner | 49BAK-XL-L   | 064229949BAK-XL-LJ4  | 41459 |
| Burn Resting Hand Accessory Kit / Replacement Liner | 49BAK-XL-R   | 064229949BAK-XL-RJG  | 41459 |
| Burn Resting Hand Accessory Kit / Replacement Liner | 49BAK-Y-L    | 064229949BAK-Y-L94   | 41459 |
| Burn Resting Hand Accessory Kit / Replacement Liner | 49BAK-Y-R    | 064229949BAK-Y-R9G   | 41459 |
| Flex Knee POP Brace                                 | 57FKPOP-L    | 064229957FKPOP-LNC   | 41065 |
| Flex Knee POP Brace                                 | 57FKPOP-M    | 064229957FKPOP-MNE   | 41065 |
| Flex Knee POP Brace                                 | 57FKPOP-S    | 064229957FKPOP-SNS   | 41065 |
| Flex Knee POP Brace                                 | 57FKPOP-XL   | 064229957FKPOP-XL48  | 41065 |
| Flex Elbow POP Brace                                | 58EPOP-ES    | 064229958EPOP-ESML   | 41053 |
| Flex Elbow POP Brace                                | 58EPOP-L     | 064229958EPOP-LEQ    | 41053 |
| Flex Elbow POP Brace                                | 58EPOP-M     | 064229958EPOP-MES    | 41053 |
| Flex Elbow POP Brace                                | 58EPOP-P     | 064229958EPOP-PEY    | 41053 |
| Flex Elbow POP Brace                                | 58EPOP-S     | 064229958EPOP-SF6    | 41053 |
| Flex Elbow POP Brace                                | 58EPOP-XL    | 064229958EPOP-XLNX   | 41053 |
| Universal Pop Knee Brace                            | 770-UPOP-P   | 0642299770-UPOP-PDU  | 41065 |
| Post Operative Pin Knee Brace                       | 77POP-Lx-C   | 064229977POP-Lx-C86  | 41065 |
| Post Operative Pin Knee Brace                       | 77POP-Lx-F   | 064229977POP-Lx-F8C  | 41065 |
| Post Operative Pin Knee Brace                       | 77POP-P      | 064229977POP-PET     | 41065 |
| Post Operative Pin Knee Brace                       | 77POP-Sx-C   | 064229977POP-Sx-C9P  | 41065 |
| Post Operative Pin Knee Brace                       | 77POP-Sx-F   | 064229977POP-Sx-F9V  | 41065 |
| Universal Arm Brace                                 | 88UAB-Av     | 064229988UAB-AvDS    | 41053 |
| Universal Arm Brace                                 | 88UAB-Lx     | 064229988UAB-LxEX    | 41053 |
| Universal Arm Brace                                 | 88UAB-P      | 064229988UAB-PC8     | 41053 |
| Universal Arm Brace                                 | 88UAB-Sx     | 064229988UAB-SxFL    | 41053 |
| Heavy Duty Pediatric Hip Orthosis                   | 96HD-BHAO-C  | 064229996HD-BHAO-CTV | 36228 |



**Declaration of Conformity Certificate**  
According to MDR 2017/745 Annex IV

| PRODUCT NAME                      | PRODUCT CODE | BASIC UDI-DI (GMN)    | GMDN  |
|-----------------------------------|--------------|-----------------------|-------|
| Heavy Duty Pediatric Hip Orthosis | 96HD-BHAO-ES | 064229996HD-BHAO-ESDE | 36228 |
| Heavy Duty Pediatric Hip Orthosis | 96HD-BHAO-I  | 064229996HD-BHAO-IU9  | 36228 |
| Heavy Duty Pediatric Hip Orthosis | 96HD-BHAO-T  | 064229996HD-BHAO-TUX  | 36228 |
| Heavy Duty Pediatric Hip Orthosis | 96HD-BHAO-Y  | 064229996HD-BHAO-YV9  | 36228 |

**Intended purpose of the device:**

Treat, immobilize, protect and/or facilitate a particular movement or section of the body involved in the pathology.

**Risk class in acc. with Annex VIII:**

Class I

HEIDI RODRIGUEZ

**31-Jan-24**

**Signature**

**Date**

**Heidi Rodriguez, Controller**  
**Printed Name / Title**