



## **EU Declaration of Conformity**

This declaration of conformity is issued under the sole responsibility of **Enraf-Nonius B.V**. Quality Management System according to EN ISO 13485:2016

| Product name:        | Manumed  |
|----------------------|--|
| Catalogue number(s): | 5500000  |
|                      | Delivery according to Manumed configurator             |
|                      | 103-5500000-4A on page 2.                              |
| Basic UDI-DI:        | 871999250855000003A                                    |
| Intended purpose:    | The Manumed is a treatment couch, which supports a     |
|                      | patient during treatment by a physiotherapist          |
| Risk class:          | I, according to rule 13 in Annex VIII of (EU) 2017/745 |
| Device marking:      | C€   |

The device covered by this declaration, in combination with its test certificate is in conformity with:

(EU) 2017/745 (Medical Device Regulation) 2006/42/EC (Machinery Directive) 2011/65/EU as amended by (EU) 2015/863 (RoHS Directive)

Any modifications to the product not authorized by Enraf-Nonius will invalidate this declaration.

#### Signed for and on behalf of Enraf-Nonius B.V.:

T. Doodkorte Commercial Director

Place: Rotterdam

Date of issue: 30 April 2021

Enraf-Nonius B.V. Vareseweg 127 3047 AT Rotterdam The Netherlands SRN (NL-MF-000000429)



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# Configuration code of Manumed Appendix 103-5500000-4A

| Type   |                                 | Upho | lstery colours  | Sectio | on Width                                     |
|--------|---------------------------------|------|-----------------|--------|--|
| L001   | Basic-2 section, head           | 012  | Black           | L5R    | 57 cm rectangular nose hole, straight leg    |
| L002   | Basic, 2-section, back          | 019  | Bordeaux        | L6R    | 67 cm rectangular nose hole, straight leg    |
| L004   | Traction, Fixed height          | 127  | Yellow          | L6T    | 67 cm rectangular nose hole, trapezium leg   |
| L005   | Bobath, 1-section, Fixed Height | 135  | Beige           | L8T    | 80 cm rectangular nose hole, trapezium leg   |
| N2xx   | Optimal 3-section               | 138  | Mint            | D5R    | 57 cm with triangle nose hole, straight leg  |
| N3xx   | Optimal 2-section               | 139  | Signal Red      | D6R    | 67 cm with triangle nose hole, straight leg  |
| N4xx   | Osteo                           | 141  | Turquois        | D6T    | 67 cm with triangle nose hole, trapezium leg |
| N5xx   | Bobath 1- & 2- section          | 155  | Jade            | D8T    | 80 cm with triangle nose hole, trapezium leg |
| N6xx   | Comfort 3-section               | 169  | Cornflower Blue | N6R    | 67 cm with small nose hole, straight leg     |
| N7xx   | Special tilt                    | 170  | Baby Blue       | ZOR    | 100 cm without nose hole, straight leg       |
| N9xx   | Traction                        | 199  | Lavender        | Z2R    | 120 cm without nose hole, straight leg       |
|        |                                 | 204  | Sirius Blue     | Z5R    | 57 cm without nose hole, straight leg        |
| Frame  | Frame colour                    |      | Grey            | Z6R    | 67 cm without nose hole, straight leg        |
| G      | Chrome                          | 406  | Petrol          | Z6T    | 67 cm without nose hole, trapezium leg       |
| N      | Grey                            | 407  | Cherry          | Z8T    | 80 cm without nose hole, trapezium leg       |
| P      | White                           | 408  | Terracotta      |        |  |
| U      | Black                           | 409  | Skin            |        |  |
|        |                                 | 410  | Anthracite      |        |  |
| Paddir | Padding                         |      | Volcano Black   |        |  |
| N      | normal                          | 812  | Grey            |        |  |
| Н      | extra hard                      | 850  | Walnut          |        |  |
| S      | extra thick and soft            | 851  | Sand            |        |  |
| L      | Luxury                          | 852  | Red             |        |  |
|        |                                 | 886  | Leaf            |        |  |
|        |                                 | 888  | Snow            |        |  |
|        |                                 | 933  | Blue            |        |  |
|        |                                 |      |                 |        |  |

#### Interface

| 0 | hydraulic  |
|---|--|
| Α | foot switch  |
| В | 2 pc foot switch   |
| C | hand switch  |
| K | table switch   |
| L | 4 button hand switch   |
| M | 4 button table switch  |
| N | foot switch + table switch   |
| R | all-around (bar $oldsymbol{\Psi}$ - couch $oldsymbol{\Psi}$ )                |
| S | all around + table switch (bar $oldsymbol{\Psi}$ - couch $oldsymbol{\Psi}$ ) |
| T | all-around (bar ↑ - couch ়)   |
| U | all-around + table switch (bar $lack \uparrow$ - couch $lack \psi$ )         |

#### ex works options

no options

options 1+2

| 1 | fixation rails               |
|---|------------------------------|
| 2 | prepared hole in seat        |
| 3 | ergo wings                   |
| 4 | foot / wheel extension 30 mm |
| 5 | options 4+1                  |
| 6 | options 4+2                  |
| 7 | options 4+3                  |
| 8 | options 4+1+2                |

#### Mains voltage

| IVIAIIIS V | oitage                           |
|------------|----------------------------------|
| C          | 230V CH 8.000N motor             |
| D          | 230V CH 10.000N motor            |
| E          | 230V EUR 8.000N motor            |
| F          | 230V EUR 10.000N motor           |
| G          | 230V UK 8.000N motor             |
| H          | 230V UK 10.000N motor            |
| J          | 115V 8.000N motor                |
| K          | 115V 10.000N motor               |
| 0          | hydraulic pump or fixed height   |
| V          | 230V EUR + safety switch         |
| W          | 230V EUR 10.000N + safety switch |
|            |                                  |

### Packaging

| 0 | cardboard top cover          |
|---|------------------------------|
| 1 | box pallet                   |
| 2 | cardboard top cover + access |
| 3 | carton box + carton blocks   |
| 4 | fumigated pallet + box       |
| D | cardboard box                |

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