

## **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:	ManuMax
Catalogue number(s):	1570000
	Delivery according to ManuMax configurator
	103-1570000-44 on page 2.
Basic UDI-DI:	871999250815700003K
Intended purpose:	The ManuMax 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:	CE

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)

> > Page 1 of 2



laration of Conform

## Configuration code of ManuMax Appendix 103-1570000-44

TTT	F	. S	с	z	A	HL	F	P	ccc	ww	N	v	м	P	0000							
Туре	Folds	Sections	Frame colour	Side cover colour	Actuator	High Low	Flexion	Uphol. padding	Uphol. colour	Section width	Breathing hole	Mains voltage	Mains Plug	Packaging	Options							
TTT EXA	Type Exami	ination		F N	Flexion No	I				ignal red /ine red			0000	Options								
MUL	Multi			н	Gas spi	ring		8	52 R	ed			0	No								
EXE	Exerci	ise		Т	Table s	witches				lue			1	Fixation rail for	r armpit /							
TIL	Tilt							5	13 G	rey Crib 5				shoulder supp								
TRA	Tractio			Р	Uphols		dding						2	Fixation rail for	or gyno							
MAN	Manip	ulation		N	Normal					ection wid	ith		_	supports								
-	F				Luxe			5		7 cm			3	Holder for Pelvic								
F 1-4	Folds	er of sections i	_	CCC	Unhala	****	lour	6		7 cm				support								
1-4		udinal directions		886	Uphols Leaf	tery co	iour	8		D cm D0 cm			4	Paperroll hold section	er toot							
	longitt	una unection		887	Fuchsia			1		20 cm				Section								
s	Sectio	ne		888	Snow				2 1	20 0111												
1-9		number of sect	ions	851	Sand			N	I B	reathing h	nole											
				779	Walnut			T		riangular												
С	Frame	e colour		812	Antracit	e		L	L	ong												
G	Grey			811	Volcano			N	I N	0												
				204	Sirius b																	
Z		cover colour		169	Cornflo		e	v		lains Volta	ige											
D	Dark			170	Baby bl			S	1	00-240 V												
L	Light			199 213	Lavend	er		N		laina Dhua												
А	Actua	tor		012	Grey Black			E		lains Plug urope												
Ĥ	Hydra			406	Cherry			Ŭ		nited King	mom											
E	Electri			407	Ocre			J		apan	uom											
-	210001			408	Petrol			Ă		orth Ameri	ca											
HL	Hiah/	Low operation	1	409	Skin			Ċ		witzerland												
AA	All Arc			410	Terraco	tta		_	_													
FF	2x Fo	ot Switch		127	Yellow			Р		ackaging												
TS		Switches		135	Beige			S	S	tandard												
HS	Hand	Switch		138	Mint																	
				155	Jade																	
				141	Turqois	е																

TTT	F	. s		с		z		4		HL			F				Р	ccc					N			v	м					Р		0000				
Type	Folds	Sections		Frame colour		Side cover colour		Actuator				H/L operation			Flexion		Upnoistery	Upholstery colour					Section width			Breathing hole	Mains					Plug	Packaging					Options
				Grey	Dark	Light	Hydraulic	Electric	All Around	2x Foot Switch	Table Switches	Hand Switch	No	Gas spring	Table Switches	Normal	Luxe		55 cm	67 cm	80 cm	100 cm	120 cm	Triangular	Long	No	100-240 \/	Eur	UK	Japan	North America	CH / Switzerland	Standard	no options	Fixation rail for armpit /	Fixation rail for gyno set	Holder for pelvic support	Paperroll holder foot section
				G	D	L	н	Е	AA	FF	TS	HS	Ν	G	Т	Ν	L	CCC	55	67	80	10	12	Т	L	Ν	S	Е	U	J	Α	С	S	0	1	2	3	4
Examination																																						
Examination	2	2	ManuMax, Examination, two fold, 2 section, back section	s	s	x		s	s	x	×	x	s			s				s				s			s	s	×	x	x	x	s	s				x
Multi Three																																						
Multi	3.	3	ManuMax, Multi, three fold, 3 section, head section	s	s	x		s	s	х	х	х	s		x	s				s				s	x		s	s	x	x	x	х	s	s				x
Multi	3 .	5	ManuMax, Multi, three fold, 5 section, head section with adjustable armrests	s	s	x		s	s	x	x	x	s		x	s				s				s	x		s	s	x	x	x	x	s	s				x

S=Standard

X=Optional

## Enraf-Nonius B.V.

Vareseweg 127 3047 AT Rotterdam The Netherlands SRN (NL-MF-000000429)

Page 2 of 2