



Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of
ENRAF-NONIUS B.V., Vareseweg 127, 3047 AT Rotterdam, The Netherlands

Quality Management System according to ISO 13485:2016, EN ISO 13485:2016
and Annex VII of European Medical Devices Directive 93/42/EEC.

Device name:	ManuXelect
Description:	Treatment couches for physical and manual therapy
Article number(s):	See appendix CFG-1550.000-49
Classification:	I (according to rule 1, Annex IX of MDD 93/42/EEC)
Record of conformity:	026-1550.000-4x ER
Device marking:	CE

We hereby declare that the above-mentioned device
complies with the European Medical Devices Directive 93/42/EEC and it has been notified to the Dutch
Ministry of Health.

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

Rotterdam, date: 28 February 2019

Signature:

A handwritten signature in blue ink, appearing to be 'Th.J. Doodkorte', written over a light blue circular stamp or watermark.

Th.J. Doodkorte
Commercial Director



Configuration code of ManuXelect
Appendix CFG-1550000-49

TFXX.PSS.GBW.MM.VAB

type	frame colour	section type	padding	upholstery colour	section width	operation	wheels	motor	packaging	option	option
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T: type

- S scissor mechanism
- L Dynatronics

F: frame colour

- G grey (RAL 7035)

XX: section type (see next 3 pages)

- 00 3 sections
- 01 2 sections, incl. head-section
- 02 2 sections, incl. back-section
- 03 traction

P: padding

- 0 normal

S: upholstery colour

- 00 grey 013
- 01 sirius blue 004
- 02 lavender 199 *
- 03 grey 812 *
- 04 blue 169 *
- 05 red 852 *
- 06 grey 013 – 80 cm *
- 07 sirius blue 004 – 80 cm *
- 08 lavender 199 – 80 cm *
- 09 sirius blue 204
- 10 grey 213

G: section width

- 0 67 cm
- 1 80 cm *

B: operation

- H hand switch
- V foot switch
- R all-around

W: wheels

- 0 no wheels
- K small wheels

MM: motor

- 00 150 kg - 230 Volt euro
- 01 150 kg - 230 Volt UK
- 02 150 kg - 115 Volt USA
- 10 250 kg - 230 Volt euro
- 11 250 kg - 230 Volt UK
- 12 250 kg - 115 Volt USA
- 13 250 kg - 115 Volt Canada
- 88 Dynatronics motor

V: packaging

- S packaging standard
- E export packaging 67 cm
- B export packaging 80 cm

A: options *

- 0 no
- 1 Paper roll holder
- A Fixation Horn
- B Gyno support Set Basic
- C Gyno Support Set Comfort
- D 1 + A
- E 1 + B
- F 1 + C
- G D + B
- H D + C
- I A + B
- J A + C

B: options

- 0 no
- 1 nose plug
- 2 Clamp Gyno/Shoulder/Armpit *
- 3 Clamp Gyno/Armpit *
- 4 Clamp Shoulder *
- 5 1 + 2 *
- 6 1 + 3 *
- 7 1 + 4 *
- 8 Saunders Device
- 9 1 + 8

* Not with traction section type (03)

Rotterdam, date: 28 February 2019

Signature:

Th.J. Doodkorte
Commercial Director