

 WESSELING BV Quality since 1958	Rev:	1.0
	Date:	1-6-2021
	Author:	D. Wesseling
	Status:	Active
TD-SCH-1 – Declaration of conformity	Page:	Pagina 1 van 4

EC DECLARATION OF CONFORMITY

We,

Manufacturer Wesseling BV
Address Venenweg 31
1161 AK Zwanenburg, The Netherlands
SRN (single registration number) NL-MF-000005894

Hereby declare under the sole responsibility that the medical devices,

Basic UDI-DI 872059802SCHQ3
Product group Scissor frame treatment tables
Model See Annex for details
Classification Class I (rule 1 and 13)
Conformity assessment procedure Annex II
Conformity route Self declaration

to which this declaration relates, are in conformity with the essential requirements and provisions formulated in (EU) 2017/745 (Medical Device Regulation).

Date : 1-6-2021
Place : Zwanenburg
Signature :



Name : D. Wesseling
Position : Director



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ANNEX – PRODUCT DETAILS

Name	Article code	UDI-DI
Praxis 1 Elite Jr. E	PRAX1JMWE	8720598020007
Praxis 1 Elite Jr. H	PRAX1JMWH	8720598020008
Praxis 1 Elite E	PRAX1EMWE	8720598020009
Praxis 1 Elite H	PRAX1EMWH	8720598020010
Praxis 2 Elite E	PRAX2EMWE	8720598020011
Praxis 2 Elite H	PRAX2EMWH	8720598020012
Praxis 3 Elite E	PRAX3EMWE	8720598020013
Praxis 3 Elite H	PRAX3EMWH	8720598020014
Praxis 4 Elite E	PRAX4EMWE	8720598020015
Praxis 4 Elite H	PRAX4EMWH	8720598020016
Praxis 3 Comfort Elite E	PRAX3CEE	8720598020017
Praxis 3 Comfort Elite H	PRAX3CEH	8720598020018
Praxis 4 Comfort Elite E	PRAX4CEE	8720598020019
Praxis 4 Comfort Elite H	PRAX4CEH	8720598020020
Praxis 3 Podo E	PRAX3PODOE	8720598020129
Praxis 3 Podo H	PRAX3PODOH	8720598020130
Praxis 4 Podo E	PRAX4PODOE	8720598020131
Praxis 4 Podo H	PRAX4PODOH	8720598020132
Premium 2	PREMIUM2	8720598020021
Premium 3	PREMIUM3	8720598020022
Kombi Elite E	KOMEMWE	8720598020023
Kombi Elite H	KOMEMWH	8720598020024
Kombi Elite S E	KOMESMWE	8720598020025
Kombi Elite S H	KOMESMWH	8720598020026
BasiX 2 E	BAS2EMWE	8720598020027
BasiX 2 H	BAS2EMWH	8720598020028
BasiX 2T E	BAS2TMWE	8720598020029
BasiX 2T H	BAS2TMWH	8720598020030
BasiX 3 E	BAS3EMWE	8720598020031
BasiX 3 H	BAS3EMWH	8720598020032
BasiX 3F E	BAS3FMWE	8720598020033
BasiX 3F H	BAS3FMWH	8720598020034
BasiX 3 BB	BAS3BB	8720598020133
BasiX 3F BB	BAS3FBB	8720598020134
BasiX 4 E	BAS4EMWE	8720598020035
BasiX 4 H	BAS4EMWH	8720598020036
BasiX 4T E	BAS4TMWE	8720598020037
BasiX 4T H	BAS4TMWH	8720598020038
BasiX 5 E	BAS5EMWE	8720598020039
BasiX 5 H	BAS5EMWH	8720598020040
BasiX 5F E	BAS5FMWE	8720598020041
BasiX 5F H	BAS5FMWH	8720598020042
BasiX 5 BB	BAS5BB	8720598020136
BasiX 5F BB	BAS5FBB	8720598020137
Bobath 1 Elite E, 90cm	BOB1E90	8720598020043
Bobath 1 Elite H, 90cm	BOB1H90	8720598020044
Bobath 1 Elite E, 100cm	BOB1E100	8720598020045
Bobath 1 Elite H, 100cm	BOB1H100	8720598020046
Bobath 1 Elite E, 110cm	BOB1E110	8720598020047
Bobath 1 Elite H, 110cm	BOB1H110	8720598020048
Bobath 1 Elite E, 120cm	BOB1E120	8720598020049
Bobath 1 Elite H, 120cm	BOB1H120	8720598020050
Bobath 2B Elite E, 90cm	BOB2BE90	8720598020051
Bobath 2B Elite H, 90cm	BOB2BH90	8720598020052

Bobath 2B Elite E, 100cm	BOB2BE100	8720598020053
Bobath 2B Elite H, 100cm	BOB2BH100	8720598020054
Bobath 2B Elite E, 110cm	BOB2BE110	8720598020055
Bobath 2B Elite H, 110cm	BOB2BH110	8720598020056
Bobath 2B Elite E, 120cm	BOB2BE120	8720598020057
Bobath 2B Elite H, 120cm	BOB2BH120	8720598020058
Bobath 2H Elite E, 90cm	BOB2HE90	8720598020059
Bobath 2H Elite H, 90cm	BOB2HH90	8720598020060
Bobath 2H Elite E, 100cm	BOB2HE100	8720598020061
Bobath 2H Elite H, 100cm	BOB2HH100	8720598020062
Bobath 2H Elite E, 110cm	BOB2HE110	8720598020063
Bobath 2H Elite H, 110cm	BOB2HH110	8720598020064
Bobath 2H Elite E, 120cm	BOB2HE120	8720598020065
Bobath 2H Elite H, 120cm	BOB2HH120	8720598020066
Plaster Compact E	PLACOM00	8720598020082
Plaster Compact H	PLACOM01	8720598020083
Plaster Compact HSE	PLACOM02	8720598020084
Plaster Compact HSH	PLACOM03	8720598020085

OPTIONS & ACCESSORIES

This DOC is valid for all options and accessories mentioned underneath.

Name	Article code
Foot switch Linak	VSCH008
Hand switch Linak	HSCH010
Connect Linak for extra switch	TSTUK02
Control lock Linak including key, for CA 30	SPERRBOX02
Electric back rest (Praxis 2, 3 & 4)	RUGELEKTRISCH
Bar switch system, white	RANDOM8
Bar switch system, black	RANDOM9
Adapters for accessories	ADAPB00
Armrest	ARMST00
Leg-/knee support	BEENS01
Foot support	VOET001
Heel support	HAKST00
paperrollholder	PAPRAX
Armrest 3D	ARMST02
Armrest can be folded back. (Praxis 3 & 4 and Podo)	ARMST03
Stainless steel disposables tray. (Kombi Elite)	RVSSP01
Perineal cut-out in sitting section. (Kombi Elite)	UITSP00
Earth potential pin settlement point.	AARDP00
Cable for earth potential pin	AARDKABEL
Different width, 70 cm	BREEDTE70
Different width, 80 cm	BREEDTE80
Thicker upholstery, 70mm	DIKKER
Nosehole (standard on BasiX)	NEUS002
Memoryfoam	LAZYFOAM0
Protective cover legsection (Praxis 3 & 4)	HOESPR00

Protective cover legsection (Premium 3)	HOESPREE00
Fixation rail 25x10mm (Praxis 3 & 4, Podo & Plaster Compact)	FIXRAIL01
Monkey Pole (Praxis 2)	PAPE003
Stamskin TOP upholstery for treatment table.	STAMSK001
Purfect upholstery for treatment table	PURFECT01