

EC declaration of conformity

MDD: Medical Device Directive 93/42/EEC as amended by Directive 2007/47/EC

(in accordance with ISO 17050-1)

1. Medical Device

Name	Infusion set
Purpose	Single use infusion set for subcutaneous infusion
Class of device(s)	Class IIb according to MDD, Annex IX, rule 8, long-term surgically invasive devices
Device category	Infusion sets for subcutaneous infusion (see product list in Attachment 1)
GMDN code and term	35833 Electric infusion pump administration set

Name	Injection port
Purpose	Single use injection port for subcutaneous injection
Class of device(s)	Class IIb according to MDD, Annex IX, rule 8, long-term surgically invasive devices
Device category	Injection ports for subcutaneous infusion (see product list in Attachment 1)
GMDN code and term	17180 Subcutaneous injection port

2. Manufacturer and European representative

Manufacturer's name	Unomedical a/s
Manufacturer's address	Aaholmvej 1-3, Osted 4320 Lejre Denmark

Other manufacturing sites	Unomedical Devices S.A de C.V Avenida Fomento Industrial, Lot 9, M3 Parque Industrial del Norte Reynosa, Tamaulipas Mexico C.P. 88736
	Unomedical Devices S.A. De C.V. Ave. Industrial Falcon, Seccion 4, Lote 7 Parque Industrial del Norte Reynosa, Tamaulipas Mexico, C.P. 88736

3. Notified body

Number	0459
Name	GMED
Address	1 rue Gaston Boissier 75724 Paris, France

4. Method to demonstrate the conformity of MDD essential requirements

Applicable Directive	MDD, Annex I and Annex II (excluding section 4)
Applicable certificates	EC Certificate no. 9559 issued by GMED ISO 13485:2016 Certificate no. 35117 issued by GMED
Technical file references	Technical file summary 3A09030 neria guard Technical file summary 3A09112 neria Technical file summary 3A09113 neria soft Technical file summary 3A09114 neria multi Technical file summary 3A09115 neria soft 90 Technical file summary 3A09116 neria detach Technical file summary 3A09117 thalaset Technical file summary 3A09122 sub Q infusion set Technical file summary 3A09108 insuflon

5. Declaration of the management concerning the CE marking

The devices meet the essential requirements set out in MDD, Annex I which apply to them and with the corresponding national legislation (Executive Order no. 1263 of 15 February 2008 concerning medical devices). CE marking is in accordance with MDD, Article 17.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Signed for and on behalf of Unomedical a/s – A ConvaTec Company:

Susanne Schwartzbach

Susanne Schwartzbach, Regulatory Affairs Team Manager

Osted, 28.APR.2020

Place and date of issue

Infusion sets

Product family: DHF-2 Comfort and comfort short

DHF#	Commercial reference	Technical product description				Item#
		connector	cannula	tubing	packaging	
2.11	neria™ soft	luer lock	13 mm	30 cm	10-pack	79-030-2522
2.11	neria™ soft	luer lock	13 mm	60 cm	10-pack	79-060-2522
2.11	neria™ soft	luer lock	13 mm	80 cm	10-pack	79-080-2522
2.11	neria™ soft	luer lock	13 mm	110 cm	10-pack	79-110-2522
2.11	neria™ soft cannula	N/A	13 mm	N/A	10-pack	76-000-2552
2.11	neria™ soft	luer lock	17 mm	60 cm	10-pack	79-060-2622
2.11	neria™ soft	luer lock	17 mm	80 cm	10-pack	79-080-2622
2.11	neria™ soft	luer lock	17 mm	110 cm	10-pack	79-110-2622
2.11	neria™ soft cannula	N/A	17 mm	N/A	10-pack	76-000-2652

Product family: DHF-5 Contact

DHF#	Commercial reference	Technical product description					Item#
		connector	cannula	tubing	packaging	gauge	
5.7	neria™	luer lock	6 mm	60 cm	10-pack	G27	78-060-2736
5.7	neria™	luer lock	6 mm	80 cm	10-pack	G27	78-080-2736
5.7	neria™	luer lock	6 mm	110 cm	10-pack	G27	78-110-2736
5.7	neria™	luer lock	8 mm	60 cm	10-pack	G27	78-060-2738
5.7	neria™	luer lock	8 mm	80 cm	10-pack	G27	78-080-2738
5.7	neria™	luer lock	8 mm	110 cm	10-pack	G27	78-110-2738
5.7	neria™	luer lock	10 mm	60 cm	10-pack	G27	78-060-2731
5.7	neria™	luer lock	10 mm	80 cm	10-pack	G27	78-080-2731
5.7	neria™	luer lock	10 mm	110 cm	10-pack	G27	78-110-2731
5.7	neria™	luer lock	12 mm	80 cm	10-pack	G27	78-080-2737
5.7	neria™	luer lock	6 mm	60 cm	10-pack	G29	78-060-2936
5.7	neria™	luer lock	6 mm	80 cm	10-pack	G29	78-080-2936
5.7	neria™	luer lock	6 mm	110 cm	10-pack	G29	78-110-2936
5.7	neria™	luer lock	8 mm	60 cm	10-pack	G29	78-060-2938
5.7	neria™	luer lock	8 mm	80 cm	10-pack	G29	78-080-2938
5.7	neria™	luer lock	8 mm	110 cm	10-pack	G29	78-110-2938
5.7	neria™	luer lock	10 mm	60 cm	10-pack	G29	78-060-2931
5.7	neria™	luer lock	10 mm	80 cm	10-pack	G29	78-080-2931
5.7	neria™	luer lock	10 mm	110 cm	10-pack	G29	78-110-2931
5.7	thalaset™	luer lock	6 mm	60 cm	10-pack	G27	71-060-2736
5.7	thalaset™	luer lock	6 mm	80 cm	10-pack	G27	71-080-2736
5.7	thalaset™	luer lock	8 mm	60 cm	10-pack	G27	71-060-2738
5.7	thalaset™	luer lock	8 mm	80 cm	10-pack	G27	71-080-2738
5.7	thalaset™	luer lock	10 mm	80 cm	10-pack	G27	71-080-2731

DHF#	Commercial reference	Technical product description					Item#
		connector	cannula	tubing	packaging	gauge	
5.7	thalaset™	luer lock	6 mm	80 cm	10-pack	G29	71-080-2936
5.7	thalaset™	luer lock	8 mm	80 cm	10-pack	G29	71-080-2938
5.7	thalaset™	luer lock	8 mm	110 cm	10-pack	G29	71-110-2938
5.7	thalaset™	luer lock	10 mm	80 cm	10-pack	G29	71-080-2931
5.7	Sub Q Infusion set	luer lock	8 mm	60 cm	10-pack	G27	71-060-2738

Product family: DHF-9 Contact detach

DHF#	Commercial reference	Technical product description					Item#
		connector	cannula	tubing	packaging	gauge	
9.5	neria™ detach	luer lock	6 mm	60 cm	10-pack	G27	78-060-2726
9.5	neria™ detach	luer lock	8 mm	60 cm	10-pack	G27	78-060-2728
9.5	neria™ detach	luer lock	8 mm	80 cm	10-pack	G27	78-080-2728

Product family: DHF-21 neria multi

DHF#	Commercial reference	Technical product description					Item#
		connector	cannula	tubing	packaging	gauge	
21	neria™ multi	luer lock	8 mm x 2	60+30 cm	10-pack	G27	721060-2738
21	neria™ multi	luer lock	8 mm x 3	60+30 cm	10-pack	G27	721060-3738
21	neria™ multi	luer lock	8 mm x 4	60+30 cm	10-pack	G27	721060-4738
21	neria™ multi	luer lock	10 mm x 2	60+30 cm	10-pack	G27	721060-2731
21	neria™ multi	luer lock	10 mm x 3	60+30 cm	10-pack	G27	721060-3731
21	neria™ multi	luer lock	10 mm x 4	60+30 cm	10-pack	G27	721060-4731
21	neria™ multi	luer lock	12 mm x 3	60+30 cm	10-pack	G27	721060-3737
21	neria™ multi	luer lock	12 mm x 4	60+30 cm	10-pack	G27	721060-4737

Product family: DHF-23 neria soft 90

DHF#	Commercial reference	Technical product description				Item#
		connector	cannula	tubing	packaging	
23	neria™ soft 90	luer lock	6 mm	30 cm	10-pack	722030-5226
23	neria™ soft 90	luer lock	6 mm	60 cm	10-pack	722060-5226
23	neria™ soft 90	luer lock	6 mm	110 cm	10-pack	722110-5226
23	neria™ soft 90	luer lock	9 mm	30 cm	10-pack	722030-5229
23	neria™ soft 90	luer lock	9 mm	60 cm	10-pack	722060-5229
23	neria™ soft 90	luer lock	9 mm	110 cm	10-pack	722110-5229
23	neria™ soft 90 cannula	N/A	9 mm	N/A	10-pack	722000-5229

Product family: DHF-25.1 Inset guard

DHF#	Commercial reference	Technical product description					Item#
		connector	cannula	tubing	packaging	color	
25.1.2	neria™ guard	luer lock	6 mm	12 cm	10-pack	N/A	704012-5226
25.1.2	neria™ guard	luer lock	6 mm	30 cm	10-pack	N/A	704030-5226
25.1.2	neria™ guard	luer lock	6 mm	60 cm	10-pack	N/A	704060-5226
25.1.2	neria™ guard	luer lock	6 mm	80 cm	10-pack	N/A	704080-5226
25.1.2	neria™ guard	luer lock	6 mm	110 cm	10-pack	N/A	704110-5226
25.1.2	neria™ guard	luer lock	9 mm	12 cm	10-pack	N/A	704012-5229
25.1.2	neria™ guard	luer lock	9 mm	30 cm	10-pack	N/A	704030-5229
25.1.2	neria™ guard	luer lock	9 mm	60 cm	10-pack	N/A	704060-5229
25.1.2	neria™ guard	luer lock	9 mm	60 cm	2-pack	N/A	702060-5229
25.1.2	neria™ guard	luer lock	9 mm	80 cm	10-pack	N/A	704080-5229
25.1.2	neria™ guard	luer lock	9 mm	80 cm	2-pack	N/A	702080-5229
25.1.2	neria™ guard	luer lock	9 mm	110 cm	10-pack	N/A	704110-5229
25.1.2	neria™ guard cannula	N/A	6 mm	N/A	10-pack	N/A	704000-5226
25.1.2	neria™ guard cannula	N/A	9 mm	N/A	10-pack	N/A	704000-5229

Injection ports

Product family: DHF-3 insuflon

DHF#	Commercial reference	Technical product description		Item#
		cannula	packaging	
3	Insuflon	18 mm	10-pack	98-000-2612