

# EC declaration of conformity

## DIRECTIVE 93/42/EEC

(in accordance with ISO 17050-1)

### 1. Medical Device

Name: Infusion set & injection port.  
Function: Single use infusion set/injection port for subcutaneous infusion.  
Class of the device(s): Class IIb according to Medical Device Directive 93/42/EEC as amended by Directive 2007/47/EC (Annex 9, rule 8, long-term surgically invasive devices).  
Device Category: Infusion sets/injection ports for subcutaneous infusion (see product list Attachment no. 1).  
GMDN code and term: 17180 Subcutaneous injection port  
35833 Electric infusion pump administration set

### 2. Manufacturer and European representative

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

Safety & Regulatory Leader: Lars Bresler, VP QA/RA, B2B, Infusion Devices & Industrial Sales

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: Medical Device Directive 93/42/EEC 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 doc. 3A09107 i-port Advance™  
Technical File Summary doc. 3A09108 Insuflon™  
Technical File Summary doc. 3A09100 MiniMed™ Mio™  
Technical File Summary doc. 3A09118 MiniMed™ Sure-T™ (Paradigm)  
Technical File Summary doc. 3A09119 MiniMed™ Quick-set™ (Paradigm)  
Technical File Summary doc. 3A09120 MiniMed™ Silhouette™ (Paradigm)  
Technical File Summary doc. 3A09124 MiniMed™ Mio™ 30  
Technical File Summary doc. 3A09137 MiniMed™ Sure T™ Infusion Set (SC1)

Technical File Summary doc. 3A09133 MiniMed™ Mio™ Infusion set (SC1)  
Technical File Summary doc. 3A09134 MiniMed™ Mio™ 30 Infusion set (SC1)  
Technical File Summary doc. 3A09135 MiniMed™ Quick set™ Infusion set (SC1)  
Technical File Summary doc. 3A09136 MiniMed™ Silhouette™ Infusion set (SC1)  
Technical File Summary doc. 3A09031 MiniMed™ Mio™ Advance  
Technical File Summary doc. 3A09034 Medtronic Extended  
Technical File Summary doc. 3A16173 MiniMed™ Mio™ Advance (SC1)

#### **5. Declaration of the management concerning the EC marking following 93/42/EEC directive**

The devices meet the essential requirements set out in Medical Device Directive 93/42/EEC annex I which apply to them and with the corresponding national legislation (Executive order no. 1263/2008 on Medical Devices).  
EC marking is in accordance with Medical Device Directive 93/42/EEC, 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:



Lars Bresler, Vice President, QA/RA



Place and date of issue

## Product family: DHF-1 Quick-set

DHF#	Commercial reference	Technical product description				Item#
		connector	cannula	tubing	packaging	
1	Quick-set®	luer lock	6 mm	60 cm	10-pack	MMT-393
1	Quick-set®	luer lock	6 mm	110 cm	10-pack	MMT-391
1	Quick-set®	luer lock	9 mm	60 cm	10-pack	MMT-392
1	Quick-set®	luer lock	9 mm	110 cm	10-pack	MMT-390
1.1	Quick-set® Paradigm®	P-CAP	6 mm	46 cm	10-pack	MMT-394
1.1	Quick-set® Paradigm®	P-CAP	6 mm	60 cm	10-pack	MMT-399
1.1	Quick-set® Paradigm®	P-CAP	6 mm	60 cm	2-pack	MMT-399T
1.1	Quick-set® Paradigm®	P-CAP	6 mm	80 cm	10-pack	MMT-387
1.1	Quick-set® Paradigm®	P-CAP	6 mm	110 cm	10-pack	MMT-398
1.1	Quick-set® Paradigm®	P-CAP	9 mm	60 cm	10-pack	MMT-397
1.1	Quick-set® Paradigm®	P-CAP	9 mm	80 cm	10-pack	MMT-386
1.1	Quick-set® Paradigm®	P-CAP	9 mm	110 cm	10-pack	MMT-396
1.6	MiniMed™ Quick set™ Infusion set	SC1	6 mm	46 cm	10-pack	MMT-394A
1.6	MiniMed™ Quick set™ Infusion set	SC1	6 mm	46 cm	10-pack	MMT-394A600
1.6	MiniMed™ Quick set™ Infusion set	SC1	6 mm	60 cm	10-pack	MMT-399A
1.6	MiniMed™ Quick set™ Infusion set	SC1	6 mm	60 cm	10-pack	MMT-399A600
1.6	MiniMed™ Quick set™ Infusion set	SC1	6 mm	80 cm	10-pack	MMT-387A
1.6	MiniMed™ Quick set™ Infusion set	SC1	6 mm	80 cm	10-pack	MMT-387A600
1.6	MiniMed™ Quick set™ Infusion set	SC1	6 mm	110 cm	10-pack	MMT-398A
1.6	MiniMed™ Quick set™ Infusion set	SC1	6 mm	110 cm	10-pack	MMT-398A600
1.6	MiniMed™ Quick set™ Infusion set	SC1	9 mm	60 cm	10-pack	MMT-397A
1.6	MiniMed™ Quick set™ Infusion set	SC1	9 mm	60 cm	10-pack	MMT-397A600
1.6	MiniMed™ Quick set™ Infusion set	SC1	9 mm	80 cm	10-pack	MMT-386A
1.6	MiniMed™ Quick set™ Infusion set	SC1	9 mm	80 cm	10-pack	MMT-386A600
1.6	MiniMed™ Quick set™ Infusion set	SC1	9 mm	110 cm	10-pack	MMT-396A
1.6	MiniMed™ Quick set™ Infusion set	SC1	9 mm	110 cm	10-pack	MMT-396A600

Product family: DHF-2 Comfort and comfort short

DHF#	Commercial reference	Technical product description				Item#
		connector	cannula	tubing	packaging	
2.2	Silhouette®	luer lock	17 mm	60 cm	10-pack	MMT-373
2.2	Silhouette®	luer lock	17 mm	110 cm	10-pack	MMT-371
2.2	Silhouette®	N/A	17 mm	N/A	10-pack	MMT-370
2.1	Silhouette®	N/A	13 mm	N/A	10-pack	MMT-369
2.3	Silhouette® Paradigm®	P-CAP	17 mm	60 cm	10-pack	MMT-378
2.3	Silhouette® Paradigm®	P-CAP	17 mm	60 cm	2-pack	MMT-378T
2.3	Silhouette® Paradigm®	P-CAP	17 mm	60 cm	2-pack	MMT-378600T
2.3	Silhouette® Paradigm®	P-CAP	17 mm	80 cm	10-pack	MMT-384
2.3	Silhouette® Paradigm®	P-CAP	17 mm	110 cm	10-pack	MMT-377
2.10	Silhouette® Paradigm®	P-CAP	13 mm	46 cm	10-pack	MMT-368
2.10	Silhouette® Paradigm®	P-CAP	13 mm	60 cm	10-pack	MMT-381
2.10	Silhouette® Paradigm®	P-CAP	13 mm	60 cm	2-pack	MMT-381T
2.10	Silhouette® Paradigm®	P-CAP	13 mm	60 cm	2-pack	MMT-381600T
2.10	Silhouette® Paradigm®	P-CAP	13 mm	80 cm	10-pack	MMT-383
2.10	Silhouette® Paradigm®	P-CAP	13 mm	110 cm	10-pack	MMT-382
2.12	MiniMed™ Silhouette™ Infusion set	SC1	17 mm	60 cm	10-pack	MMT-378A
2.12	MiniMed™ Silhouette™ Infusion set	SC1	17 mm	60 cm	10-pack	MMT-378A600
2.12	MiniMed™ Silhouette™ Infusion set	SC1	17 mm	80 cm	10-pack	MMT-384A
2.12	MiniMed™ Silhouette™ Infusion set	SC1	17 mm	80 cm	10-pack	MMT-384A600
2.12	MiniMed™ Silhouette™ Infusion set	SC1	17 mm	110 cm	10-pack	MMT-377A
2.12	MiniMed™ Silhouette™ Infusion set	SC1	17 mm	110 cm	10-pack	MMT-377A600
2.13	MiniMed™ Silhouette™ Infusion set	SC1	13 mm	46 cm	10-pack	MMT-368A
2.13	MiniMed™ Silhouette™ Infusion set	SC1	13 mm	46 cm	10-pack	MMT-368A600
2.13	MiniMed™ Silhouette™ Infusion set	SC1	13 mm	60 cm	10-pack	MMT-381A
2.13	MiniMed™ Silhouette™ Infusion set	SC1	13 mm	60 cm	10-pack	MMT-381A600
2.13	MiniMed™ Silhouette™ Infusion set	SC1	13 mm	80 cm	10-pack	MMT-383A
2.13	MiniMed™ Silhouette™ Infusion set	SC1	13 mm	80 cm	10-pack	MMT-383A600
2.13	MiniMed™ Silhouette™ Infusion set	SC1	13 mm	110 cm	10-pack	MMT-382A
2.13	MiniMed™ Silhouette™ Infusion set	SC1	13 mm	110 cm	10-pack	MMT-382A600

Product family: DHF-3 Insuflon

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

Product family: DHF-9 Contact detach

DHF#	Commercial reference	Technical product description					Item#
		connector	cannula	tubing	packaging	gauge	
9.4	Sure-T®	luer lock	6 mm	60 cm	10-pack	G29	MMT-863
9.4	Sure-T®	luer lock	6 mm	80 cm	10-pack	G29	MMT-865
9.4	Sure-T®	luer lock	8 mm	60 cm	10-pack	G29	MMT-873
9.4	Sure-T®	luer lock	8 mm	80 cm	10-pack	G29	MMT-875
9.4	Sure-T®	luer lock	10 mm	60 cm	10-pack	G29	MMT-883
9.4	Sure-T®	luer lock	10 mm	80 cm	10-pack	G29	MMT-885
9.4	Sure-T®	N/A	6 mm	N/A	10-pack	G29	MMT-860
9.4	Sure-T®	N/A	8 mm	N/A	10-pack	G29	MMT-870
9.4	Sure-T®	N/A	10 mm	N/A	10-pack	G29	MMT-880
9.1	Sure-T® Paradigm®	P-CAP	6 mm	46 cm	10-pack	G29	MMT-862
9.1	Sure-T® Paradigm®	P-CAP	6 mm	60 cm	10-pack	G29	MMT-864
9.1	Sure-T® Paradigm®	P-CAP	6 mm	60 cm	2-pack	G29	MMT-864T
9.1	Sure-T® Paradigm®	P-CAP	6 mm	80 cm	10-pack	G29	MMT-866
9.1	Sure-T® Paradigm®	P-CAP	8 mm	60 cm	10-pack	G29	MMT-874
9.1	Sure-T® Paradigm®	P-CAP	8 mm	80 cm	10-pack	G29	MMT-876
9.1	Sure-T® Paradigm®	P-CAP	10 mm	60 cm	10-pack	G29	MMT-884
9.1	Sure-T® Paradigm®	P-CAP	10 mm	80 cm	10-pack	G29	MMT-886
9.1	MiniMed™ Sure T™ Infusion set	SC1	6 mm	46 cm	10-pack	G29	MMT-862A
9.1	MiniMed™ Sure T™ Infusion set	SC1	6 mm	60 cm	10-pack	G29	MMT-864A
9.1	MiniMed™ Sure T™ Infusion set	SC1	6 mm	80 cm	10-pack	G29	MMT-866A
9.1	MiniMed™ Sure T™ Infusion set	SC1	8 mm	60 cm	10-pack	G29	MMT-874A
9.1	MiniMed™ Sure T™ Infusion set	SC1	8 mm	80 cm	10-pack	G29	MMT-876A
9.1	MiniMed™ Sure T™ Infusion set	SC1	10 mm	60 cm	10-pack	G29	MMT-884A
9.1	MiniMed™ Sure T™ Infusion set	SC1	10 mm	80 cm	10-pack	G29	MMT-886A

Product family: DHF-14 Inset II

DHF#	Commercial reference	Technical product description					Item#
		connector	cannula	tubing	packaging	color	
14.1	Mio®	P-CAP	6 mm	46 cm	10-pack	pink	MMT-921
14.1	Mio®	P-CAP	6 mm	46 cm	10-pack	blue	MMT-941
14.1	Mio®	P-CAP	6 mm	46 cm	10-pack	clear	MMT-961
14.1	Mio®	P-CAP	6 mm	60 cm	10-pack	pink	MMT-923
14.1	Mio®	P-CAP	6 mm	60 cm	10-pack	blue	MMT-943
14.1	Mio®	P-CAP	6 mm	60 cm	2-pack	blue	MMT-943T
14.1	Mio®	P-CAP	6 mm	60 cm	10-pack	clear	MMT-963
14.1	Mio®	P-CAP	6 mm	80 cm	10-pack	pink	MMT-925
14.1	Mio®	P-CAP	6 mm	80 cm	10-pack	blue	MMT-945
14.1	Mio®	P-CAP	6 mm	80 cm	10-pack	clear	MMT-965
14.1	Mio®	P-CAP	9 mm	80 cm	10-pack	clear	MMT-975
14.1	Mio®	P-CAP	9 mm	80 cm	2-pack	clear	MMT-975T
14.7	MiniMed™ Mio™ Infusion set	SC1	6 mm	46 cm	10-pack	pink	MMT-921A
14.7	MiniMed™ Mio™ Infusion set	SC1	6 mm	46 cm	10-pack	pink	MMT-921A600
14.7	MiniMed™ Mio™ Infusion set	SC1	6 mm	46 cm	10-pack	blue	MMT-941A
14.7	MiniMed™ Mio™ Infusion set	SC1	6 mm	46 cm	10-pack	blue	MMT-941A600
14.7	MiniMed™ Mio™ Infusion set	SC1	6 mm	46 cm	10-pack	clear	MMT-961A
14.7	MiniMed™ Mio™ Infusion set	SC1	6 mm	60 cm	10-pack	pink	MMT-923A
14.7	MiniMed™ Mio™ Infusion set	SC1	6 mm	60 cm	10-pack	pink	MMT-923A600
14.7	MiniMed™ Mio™ Infusion set	SC1	6 mm	60 cm	10-pack	blue	MMT-943A
14.7	MiniMed™ Mio™ Infusion set	SC1	6 mm	60 cm	10-pack	blue	MMT-943A600
14.7	MiniMed™ Mio™ Infusion set	SC1	6 mm	60 cm	10-pack	clear	MMT-963A
14.7	MiniMed™ Mio™ Infusion set	SC1	6 mm	80 cm	10-pack	pink	MMT-925A
14.7	MiniMed™ Mio™ Infusion set	SC1	6 mm	80 cm	10-pack	pink	MMT-925A600
14.7	MiniMed™ Mio™ Infusion set	SC1	6 mm	80 cm	10-pack	blue	MMT-945A
14.7	MiniMed™ Mio™ Infusion set	SC1	6 mm	80 cm	10-pack	blue	MMT-945A600
14.7	MiniMed™ Mio™ Infusion set	SC1	6 mm	80 cm	10-pack	clear	MMT-965A
14.7	MiniMed™ Mio™ Infusion set	SC1	6 mm	80 cm	10-pack	clear	MMT-965A600
14.7	MiniMed™ Mio™ Infusion set	SC1	9 mm	80 cm	10-pack	clear	MMT-975A
14.7	MiniMed™ Mio™ Infusion set	SC1	9 mm	80 cm	10-pack	clear	MMT-975A600

# Attachment 1



## Product family: DHF-15 Inset 30

DHF#	Commercial reference	Technical product description					Item#
		connector	cannula	tubing	packaging	color	
15.1	Mio™ 30	P-CAP	13 mm	60 cm	10-pack	grey	MMT-905
15.1	Mio™ 30	P-CAP	13 mm	60 cm	2-pack	grey	MMT-905T
15.1	Mio™ 30	P-CAP	13 mm	110 cm	10-pack	grey	MMT-906
15.4	MiniMed™ Mio™ 30 Infusion set	SC1	13 mm	60 cm	10-pack	grey	MMT-905A
15.4	MiniMed™ Mio™ 30 Infusion set	SC1	13 mm	60 cm	10-pack	grey	MMT-905A600
15.4	MiniMed™ Mio™ 30 Infusion set	SC1	13 mm	60 cm	2-pack	grey	MMT-905AT
15.4	MiniMed™ Mio™ 30 Infusion set	SC1	13 mm	110 cm	10-pack	grey	MMT-906A
15.4	MiniMed™ Mio™ 30 Infusion set	SC1	13 mm	110 cm	10-pack	grey	MMT-906A600

## Product family: DHF-19 i-Port Advance

DHF#	Commercial reference	Technical product description			Item#
		cannula	packaging	color	
19	i-Port Advance™	6 mm	10-pack	blue	MMT-100
19	i-Port Advance™	6 mm	2-pack	blue	MMT-100T
19	i-Port Advance™	9 mm	10-pack	blue	MMT-101
19	i-Port Advance™	9 mm	2-pack	blue	MMT-101T

## Product family: DHF-25.1 Inset Guard

DHF#	Commercial reference	Technical product description					Item#
		connector	cannula	tubing	packaging	color	
25.1	MiniMed™ Mio™ Advance	luer lock	6 mm	60 cm	10-pack	grey	MMT-247
25.1	MiniMed™ Mio™ Advance	luer lock	6 mm	60 cm	10-pack	grey	MMT-247600
25.1	MiniMed™ Mio™ Advance	luer lock	6 mm	60 cm	2-pack	grey	MMT-247T
25.1	MiniMed™ Mio™ Advance	luer lock	9 mm	110 cm	10-pack	grey	MMT-248
25.1	MiniMed™ Mio™ Advance	luer lock	9 mm	110 cm	10-pack	grey	MMT-248600
25.1.1	MiniMed™ Mio™ Advance	P-CAP	6 mm	60 cm	10-pack	grey	MMT-242
25.1.1	MiniMed™ Mio™ Advance	P-CAP	6 mm	60 cm	10-pack	grey	MMT-242600
25.1.1	MiniMed™ Mio™ Advance	P-CAP	6 mm	60 cm	2-pack	grey	MMT-242T
25.1.1	MiniMed™ Mio™ Advance	P-CAP	9 mm	60 cm	10-pack	grey	MMT-243
25.1.1	MiniMed™ Mio™ Advance	P-CAP	9 mm	60 cm	10-pack	grey	MMT-243600
25.1.1	MiniMed™ Mio™ Advance	P-CAP	9 mm	110 cm	10-pack	grey	MMT-244
25.1.1	MiniMed™ Mio™ Advance	P-CAP	9 mm	110 cm	10-pack	grey	MMT-244600
25.1.4	MiniMed™ Mio™ Advance	SC1	6 mm	110 cm	10-pack	grey	MMT-213A
25.1.4	MiniMed™ Mio™ Advance	SC1	6 mm	60 cm	10-pack	grey	MMT-242A
25.1.4	MiniMed™ Mio™ Advance	SC1	9 mm	60 cm	10-pack	grey	MMT-243A
25.1.4	MiniMed™ Mio™ Advance	SC1	9 mm	110 cm	10-pack	grey	MMT-244A

25.1.4	MiniMed™ Mio™ Advance	SC1	6 mm	60 cm	10-pack	grey	MMT-242A600
25.1.4	MiniMed™ Mio™ Advance	SC1	9 mm	60 cm	10-pack	grey	MMT-243A600
25.1.4	MiniMed™ Mio™ Advance	SC1	9 mm	110 cm	10-pack	grey	MMT-244A600
25.1.4	MiniMed™ Mio™ Advance	SC1	6 mm	60 cm	2-pack	grey	MMT-242AT

Product family: DHF-25.4 Inset Guard EWIS MDD

DHF#	Commercial reference	Technical product description				Item#
		connector	cannula	tubing	packaging	
25.4	Medtronic Extended	H-CAP	6 mm	46 cm	10-pack	MMT-430A
25.4	Medtronic Extended	H-CAP	6 mm	60 cm	10-pack	MMT-431A
25.4	Medtronic Extended	H-CAP	6 mm	80 cm	10-pack	MMT-432A
25.4	Medtronic Extended	H-CAP	6 mm	110 cm	10-pack	MMT-433A
25.4	Medtronic Extended	H-CAP	9 mm	46 cm	10-pack	MMT-440A
25.4	Medtronic Extended	H-CAP	9 mm	60 cm	10-pack	MMT-441A
25.4	Medtronic Extended	H-CAP	9 mm	80 cm	10-pack	MMT-442A
25.4	Medtronic Extended	H-CAP	9 mm	110 cm	10-pack	MMT-443A