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 3A09131 MiniMed™ Mio™ Advance Technical File Summary doc 3A09131 3A09137 MiniMed™ Sure T™ Infusion Set

Technical File Summary doc 3A09133 MiniMed™ Mio™ Infusion set
Technical File Summary doc 3A09134 MiniMed™ Mio 30™ Infusion set
Technical File Summary doc 3A09135 MiniMed™ Quick set™ Infusion set
Technical File Summary doc 3A09136 MiniMed™ Silhouette™ Infusion set
Technical File Summary doc 3A09031 MiniMed™ Mio™ Advance (DHF-25.1, DHF-25.1.1)

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:

F. [signature] (CMPO)
Lars Bresler, Vice President, QA/RA

OSTED, 04-JUL-2019
Place and date of issue

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CVR No. 6415 3315

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Attachment 1

Product description	Cust. Item#	UM-ID Item#	Classification (Europe)
Comfort			
Silhouette®, 17 mm, 23"	MMT-373	89-060-2623	IIb
Silhouette®, 17 mm, 43"	MMT-371	89-110-2623	IIb
Comfort ***(with P-Cap)***			
Silhouette® Paradigm®, 17 mm, 23"	MMT-378	89-060-2643	IIb
Silhouette® Paradigm®, 17 mm, 32"	MMT-384	89-080-2643	IIb
Silhouette® Paradigm®, 17 mm, 43"	MMT-377	89-110-2643	IIb
Silhouette® Paradigm®, 17 mm, 23", 2-pack	MMT-378T	59-060-2643	IIb
Silhouette® Paradigm®, 17 mm, 23", 2-pack	MMT-378600T	59-060-2643	IIb
Comfort ***(cannula only)***			
Silhouette®, 17 mm	MMT-370	69-000-2653	IIb
Comfort Short ***(with P-Cap)***			
Silhouette® Paradigm®, 13 mm, 18"	MMT-368	89-046-2543	IIb
Silhouette® Paradigm®, 13 mm, 23"	MMT-381	89-060-2543	IIb
Silhouette® Paradigm®, 13 mm, 32"	MMT-383	89-080-2543	IIb
Silhouette® Paradigm®, 13 mm, 43"	MMT-382	89-110-2543	IIb
Silhouette® Paradigm®, 13 mm, 23", 2-pack	MMT-381T	59-060-2543	IIb
Silhouette® Paradigm®, 13 mm, 23", 2-pack	MMT-381600T	59-060-2543	IIb
Comfort Short ***(cannula only)***			
Silhouette®, 13 mm	MMT-369	69-000-2553	IIb
Quick-set			
Quick-set®, 6 mm, 23"	MMT-393	82-060-2626	IIb
Quick-set®, 6 mm, 43"	MMT-391	82-110-2626	IIb
Quick-set®, 9 mm, 23"	MMT-392	82-060-2629	IIb
Quick-set®, 9 mm, 43"	MMT-390	82-110-2629	IIb
Quick-set ***(with P-Cap)***			
Quick-set® Paradigm®, 6 mm, 18"	MMT-394	82-046-2646	IIb
Quick-set® Paradigm®, 6 mm, 23"	MMT-399	82-060-2646	IIb
Quick-set® Paradigm®, 6 mm, 32"	MMT-387	82-080-2646	IIb
Quick-set® Paradigm®, 6 mm, 43"	MMT-398	82-110-2646	IIb
Quick-set® Paradigm®, 9 mm, 23"	MMT-397	82-060-2649	IIb
Quick-set® Paradigm®, 9 mm, 32"	MMT-386	82-080-2649	IIb
Quick-set® Paradigm®, 9 mm, 43"	MMT-396	82-110-2649	IIb
Quick-set® Paradigm®, 6 mm, 23", 2-pack	MMT-399T	52-060-2646	IIb

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Attachment 1

Product description	Cust. Item#	UM-ID Item#	Classification (Europe)
Contact Detach			
Sure-T®, 6 mm, 23"	MMT-863	81-060-2926	IIb
Sure-T®, 6 mm, 32"	MMT-865	81-080-2926	IIb
Sure-T®, 8 mm, 23"	MMT-873	81-060-2928	IIb
Sure-T®, 8 mm, 32"	MMT-875	81-080-2928	IIb
Sure-T®, 10 mm, 23"	MMT-883	81-060-2921	IIb
Sure-T®, 10 mm, 32"	MMT-885	81-080-2921	IIb
Contact Detach ***(with P-Cap)***			
Sure-T® Paradigm®, 6 mm, 18"	MMT-862	81-046-2946	IIb
Sure-T® Paradigm®, 6 mm, 23"	MMT-864	81-060-2946	IIb
Sure-T® Paradigm®, 6 mm, 32"	MMT-866	81-080-2946	IIb
Sure-T® Paradigm®, 8 mm, 23"	MMT-874	81-060-2948	IIb
Sure-T® Paradigm®, 8 mm, 32"	MMT-876	81-080-2948	IIb
Sure-T® Paradigm®, 10 mm, 23"	MMT-884	81-060-2941	IIb
Sure-T® Paradigm®, 10 mm, 32"	MMT-886	81-080-2941	IIb
Sure-T® Paradigm®, 6 mm, 23", 2-pack	MMT-864T	51-060-2946	IIb
Contact Detach ***(cannula only)***			
Sure-T®, 6 mm	MMT-860	61-000-2926	IIb
Sure-T®, 8 mm	MMT-870	61-000-2928	IIb
Sure-T®, 10 mm	MMT-880	61-000-2921	IIb
Inset II ***(with P-Cap)***			
mio®, Pink, 6 mm, 18"	MMT-921	86-046-5446	IIb
mio®, Pink, 6 mm, 23"	MMT-923	86-060-5446	IIb
mio®, Pink, 6 mm, 32"	MMT-925	86-080-5446	IIb
mio®, Blue, 6 mm, 18"	MMT-941	86-046-5146	IIb
mio®, Blue, 6 mm, 23"	MMT-943	86-060-5146	IIb
mio®, Blue, 6 mm, 32"	MMT-945	86-080-5146	IIb
mio®, Clear, 6 mm, 18"	MMT-961	86-046-5246	IIb
mio®, Clear, 6 mm, 23"	MMT-963	86-060-5246	IIb
mio®, Clear, 6 mm, 32"	MMT-965	86-080-5246	IIb
mio®, Clear, 9 mm, 32"	MMT-975	86-080-5249	IIb
mio®, Blue, 6 mm, 23", 2-pack	MMT-943T	56-060-5146	IIb
mio®, Clear, 9 mm, 32", 2-pack	MMT-975T	56-080-5249	IIb
Inset 30 ***(with P-Cap)***			
Mio™ 30, Gray, 13 mm, 23"	MMT-905	84-060-5245	IIb
Mio™ 30, Gray, 13 mm, 43"	MMT-906	84-110-5245	IIb
Mio™ 30, Gray, 13 mm, 23", 2 pack	MMT-905T	54-060-5245	IIb

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Attachment 1

Product description	Cust. Item#	UM-ID Item#	Classification (Europe)
Insuflon			
Insuflon	-	98-000-2612	IIb
i-Port Advance			
i-Port Advance™, 6 mm	MMT-100	97-000-5126	IIb
i-Port Advance™, 9 mm	MMT-101	97-000-5129	IIb
i-Port Advance™, 6 mm, 2 pack	MMT-100T	96-000-5126	IIb
i-Port Advance™, 9 mm, 2 pack	MMT-101T	96-000-5129	IIb
Mio Advance *(with P-Cap)*			
MiniMed™ Mio™ Advance™, Blue, 6 mm, 18"	MMT-211	44-046-5146	IIb
MiniMed™ Mio™ Advance™, Blue, 6 mm, 23"	MMT-212	44-060-5146	IIb
MiniMed™ Mio™ Advance™, Blue, 6 mm, 43"	MMT-213	44-110-5146	IIb
MiniMed™ Mio™ Advance™, Pink, 6 mm, 18"	MMT-231	44-046-5446	IIb
MiniMed™ Mio™ Advance™, Pink, 6 mm, 23"	MMT-232	44-060-5446	IIb
MiniMed™ Mio™ Advance™, Pink, 6 mm, 43"	MMT-233	44-110-5446	IIb
MiniMed™ Mio™ Advance™, Grey, 6 mm, 23"	MMT-242	44-060-5246	IIb
MiniMed™ Mio™ Advance™, Grey, 9 mm, 23"	MMT-243	44-060-5249	IIb
MiniMed™ Mio™ Advance™, Grey, 9 mm, 43"	MMT-244	44-110-5249	IIb
MiniMed™ Mio™ Advance™, Grey, 6 mm, 23", 2 pack	MMT-242T	442060-5246	IIb
MiniMed™ Mio™ Advance™, Grey, 6 mm, 23"	MMT-242	40-060-5246	IIb
MiniMed™ Mio™ Advance™, Grey, 9 mm, 23"	MMT-243	40-060-5249	IIb
MiniMed™ Mio™ Advance™, Grey, 9 mm, 43"	MMT-244	40-110-5249	IIb
MiniMed™ Mio™ Advance™, Grey, 6 mm, 23", 2 pack	MMT-242T	402060-5246	IIb
MiniMed™ Mio™ Advance™, Grey, 6 mm, 23"	MMT-242600	40-060-5246	IIb
MiniMed™ Mio™ Advance™, Grey, 6 mm, 23"	MMT-243600	40-060-5249	IIb
MiniMed™ Mio™ Advance™, Grey, 9 mm, 43"	MMT-244600	40-110-5249	IIb
Mio Advance			
MiniMed™ Mio™ Advance™, Grey, 6 mm, 23"	MMT-247	44-060-5226	IIb
MiniMed™ Mio™ Advance™, Grey, 9 mm, 43"	MMT-248	44-110-5229	IIb
MiniMed™ Mio™ Advance™, Grey, 6 mm, 23", 2 pack	MMT-247T	442060-5226	IIb
MiniMed™ Mio™ Advance™, Grey, 6 mm, 23"	MMT-247	40-060-5226	IIb
MiniMed™ Mio™ Advance™, Grey, 9 mm, 43"	MMT-248	40-110-5229	IIb
MiniMed™ Mio™ Advance™, Grey, 6 mm, 23", 2 pack	MMT-247T	402060-5226	IIb
MiniMed™ Mio™ Advance™, Grey, 6 mm, 23"	MMT-247600	40-060-5226	IIb
MiniMed™ Mio™ Advance™, Grey, 9 mm, 43"	MMT-248600	40-110-5229	IIb
Contact Detach (with SC1)			
MiniMed™ Sure T™ Infusion set, 6 mm, 18"	MMT-862A	81-046-2916	IIb

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Attachment 1

Product description	Cust. Item#	UM-ID Item#	Classification (Europe)
MiniMed™ Sure T™ Infusion set, 6 mm, 23"	MMT-864A	81-060-2916	IIb
MiniMed™ Sure T™ Infusion set, 6 mm, 32"	MMT-866A	81-080-2916	IIb
MiniMed™ Sure T™ Infusion set, 8 mm, 23"	MMT-874A	81-060-2918	IIb
MiniMed™ Sure T™ Infusion set, 8 mm, 32"	MMT-876A	81-080-2918	IIb
MiniMed™ Sure T™ Infusion set, 10 mm, 23"	MMT-884A	81-060-2911	IIb
MiniMed™ Sure T™ Infusion set, 10 mm, 32"	MMT-886A	81-080-2911	IIb
Inset II (with SC1)			
MiniMed™ Mio™ Infusion set, Pink, 6mm, 18"	MMT-921A	86-046-5416	IIb
MiniMed™ Mio™ Infusion set, Pink, 6mm, 23"	MMT-923A	86-060-5416	IIb
MiniMed™ Mio™ Infusion set, Pink,, 6mm, 32"	MMT-925A	86-080-5416	IIb
MiniMed™ Mio™ Infusion set, Blue, 6mm, 18"	MMT-941A	86-046-5116	IIb
MiniMed ™ Mio™ Infusion set, Blue, 6mm, 23"	MMT-943A	86-060-5116	IIb
MiniMed ™ Mio™ Infusion set, Blue, 6mm, 32"	MMT-945A	86-080-5116	IIb
MiniMed ™ Mio™ Infusion set, Clear, 6mm,18"	MMT-961A	86-046-5216	IIb
MiniMed ™ Mio™ Infusion set, Clear,6mm,23"	MMT-963A	86-060-5216	IIb
MiniMed ™ Mio™ Infusion set, Clear, 6mm,32"	MMT-965A	86-080-5216	IIb
MiniMed ™ Mio™ Infusion set, Clear, 9mm,32"	MMT-975A	86-080-5219	IIb
MiniMed ™ Mio™ Infusion set, Pink, 6mm, 18"	MMT-921A600	86-046-5416	IIb
MiniMed ™ Mio™ Infusion set, Pink, 6mm, 23"	MMT-923A600	86-060-5416	IIb
MiniMed ™ Mio™ Infusion set, Pink, 6mm, 32"	MMT-925A600	86-080-5416	IIb
MiniMed ™ Mio™ Infusion set, Blue,6mm, 18"	MMT-941A600	86-046-5116	IIb
MiniMed ™ Mio™ Infusion set, Blue, 6mm, 23"	MMT-943A600	86-060-5116	IIb
MiniMed ™ Mio™ Infusion set, Blue, 6mm, 32"	MMT-945A600	86-080-5116	IIb
MiniMed ™ Mio™ Infusion set, Clear, 6mm,32"	MMT-965A600	86-080-5216	IIb
MiniMed ™ Mio™ Infusion set, Clear, 9mm,32"	MMT-975A600	86-080-5219	IIb
Inset 30 (with SC1)			
MiniMed™Mio 30™ Infusion set, Gray, 13mm, 23"	MMT-905A	84-060-5215	IIb
MiniMed™Mio 30™ Infusion set, Gray, 13mm, 43"	MMT-906A	84-110-5215	IIb
MiniMed™Mio 30™ Infusion set, Grey, 13mm 23",2pack	MMT-905AT	54-060-5215	IIb
MiniMed™Mio 30™ Infusion set, Gray, 13mm, 23"	MMT-905A600	84-060-5215	IIb
MiniMed™Mio 30™ Infusion set, Gray, 13mm, 43"	MMT-906A600	84-110-5215	IIb
Quick set (with SC1)			
MiniMed™ Quick set™ Infusion set,9mm,32"	MMT-386A	82-080-2619	IIb
MiniMed™ Quick set™ Infusion set, 6mm, 32"	MMT-387A	82-080-2616	IIb
MiniMed™ Quick set™ Infusion set, 6mm, 18"	MMT-394A	82-046-2616	IIb
MiniMed™ Quick set™ Infusion set ,9mm, 43"	MMT-396A	82-110-2619	IIb
MiniMed™ Quick set™ Infusion set ,9mm, 23"	MMT-397A	82-060-2619	IIb

Attachment 1

Product description	Cust. Item#	UM-ID Item#	Classification (Europe)
MiniMed™ Quick set™ Infusion set,6mm, 43"	MMT-398A	82-110-2616	IIb
MiniMed™ Quick set™ Infusion set, 6mm, 23"	MMT-399A	82-060-2616	IIb
MiniMed™ Quick set™ Infusion set,9mm,32"	MMT-386A600	82-080-2619	IIb
MiniMed™ Quick set™ Infusion set, 6mm 32"	MMT-387A600	82-080-2616	IIb
MiniMed™ Quick set™ Infusion set, 6mm, 18"	MMT-394A600	82-046-2616	IIb
MiniMed™ Quick set™ Infusion set, 9mm, 43"	MMT-396A600	82-110-2619	IIb
MiniMed™ Quick set™ Infusion set, 9mm,23"	MMT-397A600	82-060-2619	IIb
MiniMed™ Quick set™ Infusion set 6mm,43"	MMT-398A600	82-110-2616	IIb
MiniMed™ Quick set™ Infusion set 6mm, 23"	MMT-399A600	82-060-2616	IIb
Comfort (with SC1)			
Minimed™ Silhouette™ Infusion set,17 mm,23"	MMT-378A	89-060-2613	IIb
Minimed™ Silhouette™ Infusion set, 17 mm,32"	MMT-384A	89-080-2613	IIb
Minimed™ Silhouette™ Infusion set, 17 mm ,43"	MMT-377A	89-110-2613	IIb
Minimed™ Silhouette™ Infusion set,17 mm,23"	MMT-378A600	89-060-2613	IIb
MiniMed™ Silhouette™ Infusion set, 17 mm,32"	MMT-384A600	89-080-2613	IIb
MiniMed™ Silhouette™ Infusion set, 17 mm,43"	MMT-377A600	89-110-2613	IIb
Comfort short (with SC1)			
MiniMed™ Silhouette™ Infusion set,13 mm ,18"	MMT-368A	89-046-2513	IIb
MiniMed™ Silhouette™ Infusion set ,13 mm ,23"	MMT-381A	89-060-2513	IIb
MiniMed™ Silhouette™ Infusion set ,13 mm,43"	MMT-382A	89-110-2513	IIb
MiniMed™ Silhouette™ Infusion set ,13 mm,32"	MMT-383A	89-080-2513	IIb
MiniMed™ Silhouette™ Infusion set,13 mm,18"	MMT-368A600	89-046-2513	IIb
MiniMed™ Silhouette™ Infusion set ,13 mm,23"	MMT-381A600	89-060-2513	IIb
MiniMed™ Silhouette™ Infusion set ,13 mm ,32"	MMT-383A600	89-080-2513	IIb
MiniMed™ Silhouette™ Infusion set ,13 mm, 43"	MMT-382A600	89-110-2513	IIb