

## ATTESTATION CE / EC CERTIFICATE

Approbation du Système Complet d'assurance Qualité/ Approval of full Quality Assurance System

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices

Pour les dispositifs de classe III, un certificat CE de conception est requis

For class III devices, a EC design certificate is required

Fabricant / Manufacturer

**UNOMEDICAL A/S**  
**Aaholmvej 1-3, Osted**  
**4320 LEJRE DENMARK**

Catégorie du(des) dispositif(s) / Device(s) category

**Sets de perfusion (canule rigide ou souple, pour insertion en biais ou droite)  
et sets pour applications thérapeutiques sous cutanés.**

*Infusion sets (rigid and soft cannula, angled and straight insertion),  
and sets for subcutaneous therapy applications.*

Voir détails sur addendum / See attachment for additional information

**GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P159827 - P600973, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.**

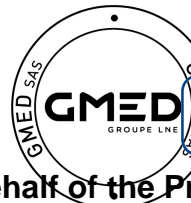
*GMED certifies that, on the basis of the results contained in the file referenced P159827 - P600973, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4*

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification

**Début de validité / Effective date : March 27th, 2020 (included)**

**Valable jusqu'au / Expiry date : May 26th, 2024 (included)**

 DocuSigned by:  
*Béatrice LYS*  
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**On behalf of the President**  
**Béatrice LYS**  
**Technical Director**

## Identification des dispositifs / Identification of devices

**Les produits couverts par ce certificat sont référencés sur la liste des produits authentifiée par GMED en date du 27 mars 2020 (11 pages).**

*The products covered by this certificate are listed on the list authenticated by GMED on March 27, 2020 (11 pages).*

## Ce certificat couvre les activités et les sites suivants / This certificate covers the following activities and sites:

- ❖ **Unomedical a/s - Aaholmvej 1-3, Osted - 4320 Lejre – Denmark :**  
**Siège social – Responsable de la mise sur le marché – Conception – Fabrication – Contrôle final**  
*Headquarter – Legal manufacturer - Design – Manufacturing – Final control*
- ❖ **Unomedical Devices S.A De C.V - Avenida Fomento Industrial, Lote 9, M3 - Parque Industrial del Norte Reynosa, Tamaulipas, Mexico C.P. 88736**  
**Fabrication - Contrôle final**  
*Manufacturing - Final control*
- ❖ **Unomedical Devices S.A. De C.V. - Avenida Industrial Falcon, Seccion 4, Lote 7 - Parque Industrial del Norte Reynosa, Tamaulipas, Mexico C.P. 88736**  
**Fabrication - Contrôle final**  
*Manufacturing - Final control*

<b>GMED</b>	<b>0459</b>
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*Béatrice LYS*

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**On behalf of the President**  
**Béatrice LYS**  
**Technical Director**

## Product family: DHF-1 Quick-set

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

GMED (0459) reconnaît que son certificat CE  
 est valide pour les dispositifs médicaux décrits  
 GMED (0459) recognizes that its CE certificate  
 is valid for the medical devices listed

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 Nolwen BOURGUIN  
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## Product family: DHF-2 Comfort

DHF#	Commercial reference	Technical product description				Item#
		connector	cannula	tubing	packaging	
2	ACCU-CHEK® TenderLink I	luer lock	17 mm	30 cm	10-pack	04541634001
2.11	neria™ soft	luer lock	17 mm	60 cm	10-pack	79-060-2622
2	ACCU-CHEK® TenderLink I	luer lock	17 mm	60 cm	10-pack	04541642001
2.2	Silhouette®	luer lock	17 mm	60 cm	10-pack	MMT-373
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
2.12	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
2.9	VariSoft™	t:lock	17 mm	60 cm	10-pack	1002830
2.11	neria™ soft	luer lock	17 mm	80 cm	10-pack	79-080-2622
2	ACCU-CHEK® TenderLink I	luer lock	17 mm	80 cm	10-pack	04541669001
2.3	Silhouette® Paradigm®	P-CAP	17 mm	80 cm	10-pack	MMT-384
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
2.11	neria™ soft	luer lock	17 mm	110 cm	10-pack	79-110-2622
2	ACCU-CHEK® TenderLink I	luer lock	17 mm	110 cm	10-pack	04541626001
2.2	Silhouette®	luer lock	17 mm	110 cm	10-pack	MMT-371
2.3	Silhouette® Paradigm®	P-CAP	17 mm	110 cm	10-pack	MMT-377
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
2.9	VariSoft™	t:lock	17 mm	110 cm	10-pack	1002832
2.11	neria™ soft cannula	N/A	17 mm	N/A	10-pack	76-000-2652
2	ACCU-CHEK® TenderLink cannula	N/A	17 mm	N/A	10-pack	05015251001
2.2	Silhouette®	N/A	17 mm	N/A	10-pack	MMT-370

GMED (0459) reconnaît que son certificat CE  
 est valide pour les dispositifs médicaux décrits  
 Document signed by: *Adrien BURQUIN*  
 GMED (0459) recognizes that its EC certificate  
 is valid for the medical devices listed

## Product family: DHF-2 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
2.1	ACCU-CHEK® TenderLink I	luer lock	13 mm	30 cm	10-pack	04541596001
2.10	Silhouette® Paradigm®	P-CAP	13 mm	46 cm	10-pack	MMT-368
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
2.11	neria™ soft	luer lock	13 mm	60 cm	10-pack	79-060-2522
2.1	ACCU-CHEK® TenderLink I	luer lock	13 mm	60 cm	10-pack	04541600001
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
2.13	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
2.8	VariSoft™	t:lock	13 mm	60 cm	10-pack	1002827
2.11	neria™ soft	luer lock	13 mm	80 cm	10-pack	79-080-2522
2.1	ACCU-CHEK® TenderLink I	luer lock	13 mm	80 cm	10-pack	04541618001
2.1	ACCU-CHEK® TenderLink I	luer lock	13 mm	80 cm	2-pack	04925718001
2.10	Silhouette® Paradigm®	P-CAP	13 mm	80 cm	10-pack	MMT-383
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
2.8	VariSoft™	t:lock	13 mm	80 cm	10-pack	1002828
2.11	neria™ soft	luer lock	13 mm	110 cm	10-pack	79-110-2522
2.1	ACCU-CHEK® TenderLink I	luer lock	13 mm	110 cm	10-pack	04541588001
2.10	Silhouette® Paradigm®	P-CAP	13 mm	110 cm	10-pack	MMT-382
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
2.11	neria™ soft cannula	N/A	13 mm	N/A	10-pack	76-000-2552
2.1	ACCU-CHEK® TenderLink cannula	N/A	13 mm	N/A	10-pack	05015260001
2.2	Silhouette®	N/A	13 mm	N/A	10-pack	MMT-369

## Product family: DHF-3 Insuflon

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

GMED (0459) reconnaît que son certificat CE  
 est valide pour les dispositifs médicaux énumérés  
 GMED (0459); recognizes that its certificate  
 is valid for the medical devices listed

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 Nolwen BOURQUIN  
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## 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	thalaset™	luer lock	6 mm	60 cm	10-pack	G27	71-060-2736
5.7	neria™	luer lock	6 mm	80 cm	10-pack	G27	78-080-2736
5.7	thalaset™	luer lock	6 mm	80 cm	10-pack	G27	71-080-2736
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	thalaset™	luer lock	8 mm	60 cm	10-pack	G27	71-060-2738
5.7	Sub Q Infusion set	luer lock	8 mm	60 cm	10-pack	G27	71-060-2738
5.7	neria™	luer lock	8 mm	80 cm	10-pack	G27	78-080-2738
5.7	thalaset™	luer lock	8 mm	80 cm	10-pack	G27	71-080-2738
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	thalaset™	luer lock	10 mm	80 cm	10-pack	G27	71-080-2731
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	thalaset™	luer lock	6 mm	80 cm	10-pack	G29	71-080-2936
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	thalaset™	luer lock	8 mm	80 cm	10-pack	G29	71-080-2938
5.7	neria™	luer lock	8 mm	110 cm	10-pack	G29	78-110-2938
5.7	thalaset™	luer lock	8 mm	110 cm	10-pack	G29	71-110-2938
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	thalaset™	luer lock	10 mm	80 cm	10-pack	G29	71-080-2931
5.7	neria™	luer lock	10 mm	110 cm	10-pack	G29	78-110-2931

GMED (0459) reconnaît que son certificat CE  
 est valide pour les dispositifs médicaux listés  
 GMED (0459) recognizes that its EC certificate  
 is valid for the medical devices listed

Documented by: *Melvin BOURGUIN*  
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## Product family: DHF-9 Contact detach

DHF#	Commercial reference	Technical product description					Item#
		connector	cannula	tubing	packaging	gauge	
9.1	Sure-T® Paradigm®	P-CAP	6 mm	46 cm	10-pack	G29	MMT-862
9.6	MiniMed™ Sure T™ Infusion set	SC1	6 mm	46 cm	10-pack	G29	MMT-862A
9.5	neria™ detach	luer lock	6 mm	60 cm	10-pack	G27	78-060-2726
9.4	Sure-T®	luer lock	6 mm	60 cm	10-pack	G29	MMT-863
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
9.6	MiniMed™ Sure T™ Infusion set	SC1	6 mm	60 cm	10-pack	G29	MMT-864A
9.3	TruSteel™	t:lock	6 mm	60 cm	10-pack	G29	1002833
9.4	Sure-T®	luer lock	6 mm	80 cm	10-pack	G29	MMT-865
9.1	Sure-T® Paradigm®	P-CAP	6 mm	80 cm	10-pack	G29	MMT-866
9.6	MiniMed™ Sure T™ Infusion set	SC1	6 mm	80 cm	10-pack	G29	MMT-866A
9.3	TruSteel™	t:lock	6 mm	80 cm	10-pack	G29	1002834
9.5	neria™ detach	luer lock	8 mm	60 cm	10-pack	G27	78-060-2728
9.4	Sure-T®	luer lock	8 mm	60 cm	10-pack	G29	MMT-873
9.1	Sure-T® Paradigm®	P-CAP	8 mm	60 cm	10-pack	G29	MMT-874
9.6	MiniMed™ Sure T™ Infusion set	SC1	8 mm	60 cm	10-pack	G29	MMT-874A
9.3	TruSteel™	t:lock	8 mm	60 cm	10-pack	G29	1002835
9.5	neria™ detach	luer lock	8 mm	80 cm	10-pack	G27	78-080-2728
9.4	Sure-T®	luer lock	8 mm	80 cm	10-pack	G29	MMT-875
9.1	Sure-T® Paradigm®	P-CAP	8 mm	80 cm	10-pack	G29	MMT-876
9.6	MiniMed™ Sure T™ Infusion set	SC1	8 mm	80 cm	10-pack	G29	MMT-876A
9.3	TruSteel™	t:lock	8 mm	80 cm	10-pack	G29	1002836
9.4	Sure-T®	luer lock	10 mm	60 cm	10-pack	G29	MMT-883
9.1	Sure-T® Paradigm®	P-CAP	10 mm	60 cm	10-pack	G29	MMT-884
9.6	MiniMed™ Sure T™ Infusion set	SC1	10 mm	60 cm	10-pack	G29	MMT-884A
9.4	Sure-T®	luer lock	10 mm	80 cm	10-pack	G29	MMT-885
9.1	Sure-T® Paradigm®	P-CAP	10 mm	80 cm	10-pack	G29	MMT-886
9.6	MiniMed™ Sure T™ Infusion set	SC1	10 mm	80 cm	10-pack	G29	MMT-886A
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

GMED (0459) reconnaît que son certificat CE  
est valide pour les dispositifs médicaux décrits  
Documented by  
Nolven BOURQUIN  
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## 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
14.7	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
14.1	Mio®	P-CAP	6 mm	46 cm	10-pack	blue	MMT-941
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
14.1	Mio®	P-CAP	6 mm	46 cm	10-pack	clear	MMT-961
14.7	MiniMed™ Mio™ Infusion set	SC1	6 mm	46 cm	10-pack	clear	MMT-961A
14.5	YpsoPump® Inset	Y-CAP	6 mm	46 cm	10-pack	grey	UL1861
14.6	Dana inset™ II	S-CAP	6 mm	46 cm	10-pack	grey	86-046-52C6MSOOI
14	inset™ II	luer lock	6 mm	60 cm	10-pack	pink	Inner box: 100-410-52 Outer box: 100-410-02
14.1	Mio®	P-CAP	6 mm	60 cm	10-pack	pink	MMT-923
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	inset™ II	luer lock	6 mm	60 cm	10-pack	blue	Inner box: 100-410-51 Outer box: 100-410-01
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
14.7	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	inset™ II	luer lock	6 mm	60 cm	10-pack	grey	Inner box: 100-410-50 Outer box: 100-410-00
14	inset™ II	luer lock	6 mm	60 cm	2-pack	grey	Inner box: 100-410-50 Outer box: 100-410-20
14.1	Mio®	P-CAP	6 mm	60 cm	10-pack	clear	MMT-963
14.7	MiniMed™ Mio™ Infusion set	SC1	6 mm	60 cm	10-pack	clear	MMT-963A
14.3	AutoSoft90™	t:lock	6 mm	60 cm	10-pack	pink	1002821
14.3	AutoSoft90™	t:lock	6 mm	60 cm	10-pack	blue	1002823
14.3	AutoSoft90™	t:lock	6 mm	60 cm	10-pack	grey	1002817
14.5	YpsoPump® Inset	Y-CAP	6 mm	60 cm	10-pack	grey	UL2461
14.6	Dana inset™ II	S-CAP	6 mm	60 cm	10-pack	grey	86-060-52C6MSOOI
14.1	Mio®	P-CAP	6 mm	80 cm	10-pack	pink	MMT-925
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
14.1	Mio®	P-CAP	6 mm	80 cm	10-pack	blue	MMT-945
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
14.1	Mio®	P-CAP	6 mm	80 cm	10-pack	clear	MMT-965
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
14.5	YpsoPump® Inset	Y-CAP	6 mm	80 cm	10-pack	grey	UL3161



DHF#	Commercial reference	Technical product description					Item#
		connector	cannula	tubing	packaging	color	
14.6	Dana inset™ II	S-CAP	6 mm	80 cm	10-pack	grey	86-080-52C6MSOOI
14	inset™ II	luer lock	6 mm	110 cm	10-pack	grey	Inner box: 100-412-50 Outer box: 100-412-00
14.3	AutoSoft90™	t:lock	6 mm	110 cm	10-pack	grey	1002818
14.5	YpsoPump® Inset	Y-CAP	6 mm	110 cm	10-pack	grey	UL4361
14.6	Dana inset™ II	S-CAP	6 mm	110 cm	10-pack	grey	86-110-52C6MSOOI
14.5	YpsoPump® Inset	Y-CAP	9 mm	46 cm	10-pack	grey	UL1891
14.6	Dana inset™ II	S-CAP	9 mm	46 cm	10-pack	grey	86-046-52C9MSOOI
14	inset™ II	luer lock	9 mm	60 cm	10-pack	pink	Inner box: 100-411-52 Outer box: 100-411-02
14.3	AutoSoft90™	t:lock	9 mm	60 cm	10-pack	pink	1002822
14	inset™ II	luer lock	9 mm	60 cm	10-pack	blue	Inner box: 100-411-51 Outer box: 100-411-01
14.3	AutoSoft90™	t:lock	9 mm	60 cm	10-pack	blue	1002824
14	inset™ II	luer lock	9 mm	60 cm	10-pack	grey	Inner box: 100-411-50 Outer box: 100-411-00
14	inset™ II	luer lock	9 mm	60 cm	2-pack	grey	Inner box: 100-411-50 Outer box: 100-411-20
14.3	AutoSoft90™	t:lock	9 mm	60 cm	10-pack	grey	1002819
14.5	YpsoPump® Inset	Y-CAP	9 mm	60 cm	10-pack	grey	UL2491
14.6	Dana inset™ II	S-CAP	9 mm	60 cm	10-pack	grey	86-060-52C9MSOOI
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	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
14.5	YpsoPump® Inset	Y-CAP	9 mm	80 cm	10-pack	grey	UL3191
14.6	Dana inset™ II	S-CAP	9 mm	80 cm	10-pack	grey	86-080-52C9MSOOI
14	inset™ II	luer lock	9 mm	110 cm	10-pack	grey	Inner box: 100-413-50 Outer box: 100-413-00
14.3	AutoSoft90™	t:lock	9 mm	110 cm	10-pack	grey	1002820
14.5	YpsoPump® Inset	Y-CAP	9 mm	110 cm	10-pack	grey	UL4391
14.6	Dana inset™ II	S-CAP	9 mm	110 cm	10-pack	grey	86-110-52C9MSOOI

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## Product family: DHF-15 Inset 30

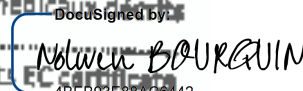
DHF #	Commercial reference	Technical product description					Item#
		connector	cannula	tubing	packaging	color	
15	inset™ 30 tubing	luer lock	13 mm	60 cm	10-pack	blue	cannula: 100-396-51 tubing: 100-396-54 Outer box: 100-396-01
15	inset™ 30 tubing	luer lock	13 mm	60 cm	10-pack	pink	cannula: 100-396-52 tubing: 100-396-55 Outer box: 100-396-02
15	inset™ 30 tubing	luer lock	13 mm	60 cm	10-pack	grey	cannula: 100-396-50 tubing: 100-396-53 Outer box: 100-396-00
15	inset™ 30 tubing	luer lock	13 mm	60 cm	2-pack	grey	cannula: 100-396-50 tubing: 100-396-53 Outer box: 100-396-20
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
15.4	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
15.2	AutoSoft30™	t:lock	13 mm	60 cm	10-pack	grey	1002825
15	inset™ 30 tubing	luer lock	13 mm	110 cm	10-pack	grey	cannula: 100-396-50 tubing: 100-396-56 Outer box: 100-396-03
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	110 cm	10-pack	grey	MMT-906A
15.4	MiniMed™ Mio™ 30 Infusion set	SC1	13 mm	110 cm	10-pack	grey	MMT-906A600
15.2	AutoSoft30™	t:lock	13 mm	110 cm	10-pack	grey	1002826

## 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

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GMED (0459) recognizes that its EC certificate is valid for the medical devices listed

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## 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

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## 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	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
25.1.1	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
25.1.4	MiniMed™ Mio™ Advance	SC1	6 mm	60 cm	10-pack	grey	MMT-242A
25.1.4	MiniMed™ Mio™ Advance	SC1	6 mm	60 cm	10-pack	grey	MMT-242A600
25.1.4	MiniMed™ Mio™ Advance	SC1	6 mm	60 cm	2-pack	grey	MMT-242AT
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
25.1.4	MiniMed™ Mio™ Advance	SC1	6 mm	110 cm	10-pack	grey	MMT-213A
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
25.1.1	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
25.1.4	MiniMed™ Mio™ Advance	SC1	9 mm	60 cm	10-pack	grey	MMT-243A
25.1.4	MiniMed™ Mio™ Advance	SC1	9 mm	60 cm	10-pack	grey	MMT-243A600
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	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	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	9 mm	110 cm	10-pack	grey	MMT-244A
25.1.4	MiniMed™ Mio™ Advance	SC1	9 mm	110 cm	10-pack	grey	MMT-244A600
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

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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

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

*Lars Bresler*

18-MAR-2020

Lars Bresler, Vice President, QA/RA

Date

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DocuSigned by:

*Nolven BOURQUIN*

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