

Paris, le 06 mars 2024
Paris, March 6, 2024

Lettre de confirmation émise par l'Organisme Notifié
Notified Body Confirmation Letter
Référence/Reference: 39615 rev. 0

[ENGLISH BELOW]

A qui de droit,

Confirmation du statut d'une demande formelle, d'un accord écrit et de la surveillance appropriée dans le cadre du règlement UE 2023/607 modifiant les règlements (UE) 2017/745 et (UE) 2017/746 en ce qui concerne les dispositions transitoires relatives à certains dispositifs médicaux et dispositifs médicaux de diagnostic in vitro.

Cette lettre confirme que, **GMED SAS**, Organisme Notifié désigné au titre du règlement (UE) 2017/745 (ci-après : MDR) et identifié par le numéro **0459** sur NANDO, a reçu une demande formelle de certification conformément à l'annexe VII, section 4.3, premier alinéa, et a signé un accord écrit (contrat) conformément à l'annexe VII, section 4.3, deuxième alinéa dudit Règlement avec le fabricant nommé ci-dessous :

UNOMEDICAL a/s
Aaholmvej 1-3, Osted
4320 Lejre
Denmark
SRN: DK-MF-000002447

Les dispositifs couverts par la demande formelle et l'accord écrit mentionnés ci-dessus sont identifiés dans les tableaux suivants. Le tableau 1 identifie les dispositifs pour lesquels une demande formelle a été reçue, un accord écrit conclu et pour lesquels GMED SAS est également responsable de la surveillance appropriée des dispositifs correspondants au titre de la directive applicable. Le tableau 2 identifie les dispositifs pour lesquels une demande de RIM a été reçue et un accord écrit conclu, mais pour lesquels GMED SAS n'est pas encore responsable de la surveillance appropriée des dispositifs correspondants au titre de la directive applicable.

Dans le cas de dispositifs couverts par des certificats délivrés au titre de la directive 90/385/CEE (AIMDD) ou de la directive 93/42/CEE (MDD) qui ont expiré après le 26 mai 2021 et avant le 20 mars 2023, sans avoir été retirés, cette lettre confirme également que le fabricant a signé l'accord écrit avant la date d'expiration desdits certificats ou a fourni la preuve qu'une Autorité Compétente d'un État Membre a accordé une dérogation conformément à l'article 59(1) du règlement (UE) 2017/745 ou a demandé conformément à l'article 97(1) du règlement (UE) 2017/745, de mettre en œuvre la procédure d'évaluation de la conformité applicable, avant le 20 mars 2023 pour les dispositifs concernés.

Les délais de transition qui s'appliquent aux dispositifs couverts par la présente lettre, sous réserve que le fabricant continue de respecter les autres conditions spécifiées à l'article 120.3 du Règlement (UE) 2017/745 (amendé par le Règlement (UE) 2023/607), sont indiqués ci-dessous :

- 26 mai 2026 pour les dispositifs implantables sur mesure de classe III
- 31 décembre 2027 pour les dispositifs de classe III et les dispositifs implantables de classe IIb à l'exclusion des technologies bien établies (WET - sutures, agrafes, obturations dentaires, appareils dentaires, couronnes dentaires, vis, coins, plaques, fils, broches, clips et connecteurs)
- 31 décembre 2028 pour les autres dispositifs de classe IIb, de classe IIa, de classe I mis sur le marché à l'état stérile, ayant une fonction de mesurage
- 31 décembre 2028 pour les dispositifs dont l'évaluation de la conformité au titre de la Directive 93/42/CEE ne nécessitait pas l'intervention d'un organisme notifié (par exemple instruments chirurgicaux réutilisables de classe I).

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

*This letter confirms that, **GMED SAS**, a Notified Body designated against Regulation (EU) 2017/745 (hereafter: MDR) and identified by the number **0459** on NANDO, has received a formal application for certification in accordance with Annex VII, section 4.3, first subparagraph, and has signed a written agreement (contract) in accordance with Annex VII, section 4.3, second paragraph of the said regulation with the manufacturer named below:*

**UNOMEDICAL a/s
Aaholmvej 1-3, Østed
4320 Lejre
Denmark
SRN: DK-MF-000002447**

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the written agreement was concluded by the date of certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function.
- 31 December 2028 for devices whose conformity assessment under Directive 93/42/EEC did not require the intervention of a notified body (e.g. class I reusable surgical instruments).

Pour le compte de GMED SAS,
On behalf of GMED SAS,

DocuSigned by:
Maud Plombas
93E40A*392D24B*

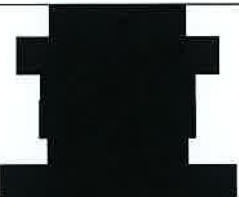
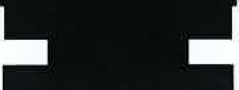
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Lionel DREUX
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Maud PLOMBAS

Responsable du Département DMI VOG
VOG IMD Department Manager

Tableau 1 : Dispositifs couverts par la présente lettre et pour lesquels GMED SAS est également responsable de la surveillance appropriée des dispositifs correspondants dans le cadre de la Directive applicable

Table 1: Devices covered by this letter and for which GMED SAS is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive

Device formally for which the formal application was lodged and/or the agreement signed	Risk class of the device according to Annex VIII of Regulation (EU) 2017/745	Identification of the device certified under Directive 90/385/EEC or 93/42/EEC and intended to be substituted, if applicable	Reference(s) of the certificate(s) under Directive 90/385/EEC or 93/42/EEC
neria guard 5805244ID0007DX	IIb	N/A	EC certificate n° 9559 rev. 32
	IIb	N/A	EC certificate n° 9559 rev. 32
	IIb	N/A	EC certificate n° 9559 rev. 32

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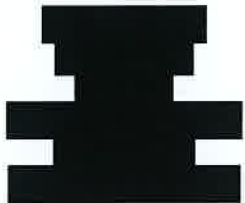
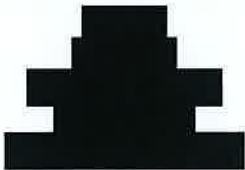
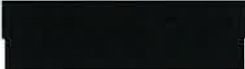
Device formally for which the formal application was lodged and/or the agreement signed	Risk class of the device according to Annex VIII of Regulation (EU) 2017/745	Identification of the device certified under Directive 90/385/EEC or 93/42/EEC and intended to be substituted, if applicable	Reference(s) of the certificate(s) under Directive 90/385/EEC or 93/42/EEC
	IIb	N/A	EC certificate n° 9559 rev. 32
	IIb	N/A	EC certificate n° 9559 rev. 32
neria soft 5805244ID0005DT	IIb	N/A	EC certificate n° 9559 rev. 32
Neria 5805244ID0003DP	IIb	N/A	EC certificate n° 9559 rev. 32
neria multi 5805244ID0008DZ	IIb	N/A	EC certificate n° 9559 rev. 32
	IIb	N/A	EC certificate n° 9559 rev. 32
	IIb	N/A	EC certificate n° 9559 rev. 32
	IIb	N/A	EC certificate n° 9559 rev. 32
	IIb	N/A	EC certificate n° 9559 rev. 32

Tableau 2 : Dispositifs couverts par la présente lettre et pour lesquels GMED SAS n'est pas encore responsable de la surveillance appropriée des dispositifs correspondants dans le cadre de la Directive applicable

Table 2: Devices covered by this letter and for which GMED SAS is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and/or Basic UDI-DI (under MDR application)	Risk class of the device according to Annex VIII of Regulation (EU) 2017/745	Identification of the device certified under Directive 90/385/EEC or 93/42/EEC and intended to be substituted, if applicable	Reference(s) of the certificate(s) under Directive 90/385/EEC or 93/42/EEC*
NA	NA	NA	NA

Historique de révision de la lettre
Confirmation Letter Revision History

Date	Révision/Revision	Action
06/03/2024	39615 rev. 0	Première émission <i>Initial issuance</i>

Pour toute question concernant le statut ou la validité de cette lettre, veuillez contacter : g-med-certificats@lne-gmed.com

For any query about the status of validity of this letter, please contact : g-med-certificats@lne-gmed.com

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 document complémentaire GMED / See GMED additional document
n° 37058**

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P600973 - P601557, 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 P600973 - P601557, 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 : April 26th, 2021 (included)

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



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

Ce document complémentaire GMED n° 37058 rev. 6 atteste de la validité du certificat CE n° 9559 rev. 32 au regard des informations listées ci-dessous.

This GMED additional document N° 37058 rev. 6 attests to the validity of CE certificate n° 9559 rev. 32 with regard to the information listed below.

Fabricant / Manufacturer:

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

Identification des dispositifs / Identification of devices

Product family: DHF-1 Quick-set

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

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 Béatrice LYS
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On behalf of the President
Béatrice LYS
Technical Director

Quick-set®	luer lock	9 mm	60 cm	10-pack	MMT-392
Quick-set® Paradigm®	P-CAP	9 mm	60 cm	10-pack	MMT-397
MiniMed™ Quick set™ Infusion set	SC1	9 mm	60 cm	10-pack	MMT-397A
MiniMed™ Quick set™ Infusion set	SC1	9 mm	60 cm	10-pack	MMT-397A600
Quick-set® Paradigm®	P-CAP	9 mm	80 cm	10-pack	MMT-386
MiniMed™ Quick set™ Infusion set	SC1	9 mm	80 cm	10-pack	MMT-386A
MiniMed™ Quick set™ Infusion set	SC1	9 mm	80 cm	10-pack	MMT-386A600
Quick-set®	luer lock	9 mm	110 cm	10-pack	MMT-390
Quick-set® Paradigm®	P-CAP	9 mm	110 cm	10-pack	MMT-396
MiniMed™ Quick set™ Infusion set	SC1	9 mm	110 cm	10-pack	MMT-396A
MiniMed™ Quick set™ Infusion set	SC1	9 mm	110 cm	10-pack	MMT-396A600

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DocuSigned by:

Béatrice LYS

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On behalf of the President
Béatrice LYS
Technical Director

Product family: DHF-2 Comfort

Commercial reference	Technical product description				Item#
	connector	cannula	tubing	packaging	
ACCU-CHEK® TenderLink I	luer lock	17 mm	30 cm	10-pack	04541634001
neria™ soft	luer lock	17 mm	60 cm	10-pack	79-060-2622
ACCU-CHEK® TenderLink I	luer lock	17 mm	60 cm	10-pack	04541642001
Silhouette®	luer lock	17 mm	60 cm	10-pack	MMT-373
Silhouette® Paradigm®	P-CAP	17 mm	60 cm	10-pack	MMT-378
Silhouette® Paradigm®	P-CAP	17 mm	60 cm	2-pack	MMT-378T
Silhouette® Paradigm®	P-CAP	17 mm	60 cm	2-pack	MMT-378600T
MiniMed™ Silhouette™ Infusion set	SC1	17 mm	60 cm	10-pack	MMT-378A
MiniMed™ Silhouette™ Infusion set	SC1	17 mm	60 cm	10-pack	MMT-378A600
MiniMed™ Silhouette™ Infusion set	SC1	17 mm	60 cm	2-pack	MMT-378AT
VariSoft™	t:lock	17 mm	60 cm	10-pack	1002830
neria™ soft	luer lock	17 mm	80 cm	10-pack	79-080-2622
ACCU-CHEK® TenderLink I	luer lock	17 mm	80 cm	10-pack	04541669001
Silhouette® Paradigm®	P-CAP	17 mm	80 cm	10-pack	MMT-384
MiniMed™ Silhouette™ Infusion set	SC1	17 mm	80 cm	10-pack	MMT-384A
MiniMed™ Silhouette™ Infusion set	SC1	17 mm	80 cm	10-pack	MMT-384A600
neria™ soft	luer lock	17 mm	110 cm	10-pack	79-110-2622
ACCU-CHEK® TenderLink I	luer lock	17 mm	110 cm	10-pack	04541626001
Silhouette®	luer lock	17 mm	110 cm	10-pack	MMT-371
Silhouette® Paradigm®	P-CAP	17 mm	110 cm	10-pack	MMT-377
MiniMed™ Silhouette™ Infusion set	SC1	17 mm	110 cm	10-pack	MMT-377A
MiniMed™ Silhouette™ Infusion set	SC1	17 mm	110 cm	10-pack	MMT-377A600
VariSoft™	t:lock	17 mm	110 cm	10-pack	1002832
neria™ soft cannula	N/A	17 mm	N/A	10-pack	76-000-2652
ACCU-CHEK® TenderLink cannula	N/A	17 mm	N/A	10-pack	05015251001
Silhouette®	N/A	17 mm	N/A	10-pack	MMT-370

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On behalf of the President
Béatrice LYS
Technical Director

Product family: DHF-2 Comfort short

Commercial reference	Technical product description				Item#
	connector	cannula	tubing	packaging	
neria™ soft	luer lock	13 mm	30 cm	10-pack	79-030-2522
ACCU-CHEK® TenderLink I	luer lock	13 mm	30 cm	10-pack	04541596001
Silhouette® Paradigm®	P-CAP	13 mm	46 cm	10-pack	MMT-368
MiniMed™ Silhouette™ Infusion set	SC1	13 mm	46 cm	10-pack	MMT-368A
MiniMed™ Silhouette™ Infusion set	SC1	13 mm	46 cm	10-pack	MMT-368A600
neria™ soft	luer lock	13 mm	60 cm	10-pack	79-060-2522
ACCU-CHEK® TenderLink I	luer lock	13 mm	60 cm	10-pack	04541600001
Silhouette® Paradigm®	P-CAP	13 mm	60 cm	10-pack	MMT-381
Silhouette® Paradigm®	P-CAP	13 mm	60 cm	2-pack	MMT-381T
Silhouette® Paradigm®	P-CAP	13 mm	60 cm	2-pack	MMT-381600T
MiniMed™ Silhouette™ Infusion set	SC1	13 mm	60 cm	10-pack	MMT-381A
MiniMed™ Silhouette™ Infusion set	SC1	13 mm	60 cm	10-pack	MMT-381A600
MiniMed™ Silhouette™ Infusion set	SC1	13 mm	60 cm	2-pack	MMT-381AT
VariSoft™	t:lock	13 mm	60 cm	10-pack	1002827
neria™ soft	luer lock	13 mm	80 cm	10-pack	79-080-2522
ACCU-CHEK® TenderLink I	luer lock	13 mm	80 cm	10-pack	04541618001
ACCU-CHEK® TenderLink I	luer lock	13 mm	80 cm	2-pack	04925718001
Silhouette® Paradigm®	P-CAP	13 mm	80 cm	10-pack	MMT-383
MiniMed™ Silhouette™ Infusion set	SC1	13 mm	80 cm	10-pack	MMT-383A
MiniMed™ Silhouette™ Infusion set	SC1	13 mm	80 cm	10-pack	MMT-383A600
VariSoft™	t:lock	13 mm	80 cm	10-pack	1002828
neria™ soft	luer lock	13 mm	110 cm	10-pack	79-110-2522
ACCU-CHEK® TenderLink I	luer lock	13 mm	110 cm	10-pack	04541588001
Silhouette® Paradigm®	P-CAP	13 mm	110 cm	10-pack	MMT-382
MiniMed™ Silhouette™ Infusion set	SC1	13 mm	110 cm	10-pack	MMT-382A
MiniMed™ Silhouette™ Infusion set	SC1	13 mm	110 cm	10-pack	MMT-382A600
neria™ soft cannula	N/A	13 mm	N/A	10-pack	76-000-2552
ACCU-CHEK® TenderLink cannula	N/A	13 mm	N/A	10-pack	05015260001
Silhouette®	N/A	13 mm	N/A	10-pack	MMT-369

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On behalf of the President
Béatrice LYS
Technical Director

Product family: DHF-3 Insuflon

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

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On behalf of the President
Béatrice LYS
Technical Director

Product family: DHF-5 Contact

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

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On behalf of the President
Béatrice LYS
Technical Director

Product family: DHF-9 Contact detach

Commercial reference	Technical product description					Item#
	connector	cannula	tubing	packaging	gauge	
Sure-T® Paradigm®	P-CAP	6 mm	46 cm	10-pack	G29	MMT-862
MiniMed™ Sure T™ Infusion set	SC1	6 mm	46 cm	10-pack	G29	MMT-862A
neria™ detach	luer lock	6 mm	60 cm	10-pack	G27	78-060-2726
Sure-T®	luer lock	6 mm	60 cm	10-pack	G29	MMT-863
Sure-T® Paradigm®	P-CAP	6 mm	60 cm	10-pack	G29	MMT-864
Sure-T® Paradigm®	P-CAP	6 mm	60 cm	2-pack	G29	MMT-864T
MiniMed™ Sure T™ Infusion set	SC1	6 mm	60 cm	10-pack	G29	MMT-864A
MiniMed™ Sure T™ Infusion set	SC1	6 mm	60 cm	2-pack	G29	MMT-864AT
TruSteel™	t:lock	6 mm	60 cm	10-pack	G29	1002833
Sure-T®	luer lock	6 mm	80 cm	10-pack	G29	MMT-865
Sure-T® Paradigm®	P-CAP	6 mm	80 cm	10-pack	G29	MMT-866
MiniMed™ Sure T™ Infusion set	SC1	6 mm	80 cm	10-pack	G29	MMT-866A
TruSteel™	t:lock	6 mm	80 cm	10-pack	G29	1002834
neria™ detach	luer lock	8 mm	60 cm	10-pack	G27	78-060-2728
Sure-T®	luer lock	8 mm	60 cm	10-pack	G29	MMT-873
Sure-T® Paradigm®	P-CAP	8 mm	60 cm	10-pack	G29	MMT-874
MiniMed™ Sure T™ Infusion set	SC1	8 mm	60 cm	10-pack	G29	MMT-874A
TruSteel™	t:lock	8 mm	60 cm	10-pack	G29	1002835
neria™ detach	luer lock	8 mm	80 cm	10-pack	G27	78-080-2728
Sure-T®	luer lock	8 mm	80 cm	10-pack	G29	MMT-875
Sure-T® Paradigm®	P-CAP	8 mm	80 cm	10-pack	G29	MMT-876
MiniMed™ Sure T™ Infusion set	SC1	8 mm	80 cm	10-pack	G29	MMT-876A
TruSteel™	t:lock	8 mm	80 cm	10-pack	G29	1002836
Sure-T®	luer lock	10 mm	60 cm	10-pack	G29	MMT-883
Sure-T® Paradigm®	P-CAP	10 mm	60 cm	10-pack	G29	MMT-884
MiniMed™ Sure T™ Infusion set	SC1	10 mm	60 cm	10-pack	G29	MMT-884A
Sure-T®	luer lock	10 mm	80 cm	10-pack	G29	MMT-885
Sure-T® Paradigm®	P-CAP	10 mm	80 cm	10-pack	G29	MMT-886
MiniMed™ Sure T™ Infusion set	SC1	10 mm	80 cm	10-pack	G29	MMT-886A
Sure-T®	N/A	6 mm	N/A	10-pack	G29	MMT-860
Sure-T®	N/A	8 mm	N/A	10-pack	G29	MMT-870
Sure-T®	N/A	10 mm	N/A	10-pack	G29	MMT-880

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Béatrice LYS

EF33BDABBA04A3...

On behalf of the President
Béatrice LYS
Technical Director

Product family: DHF-14 Inset II

Commercial reference	Technical product description					Item#
	connector	cannula	tubing	packaging	color	
Mio®	P-CAP	6 mm	46 cm	10-pack	pink	MMT-921
MiniMed™ Mio™ Infusion set	SC1	6 mm	46 cm	10-pack	pink	MMT-921A
MiniMed™ Mio™ Infusion set	SC1	6 mm	46 cm	10-pack	pink	MMT-921A600
Mio®	P-CAP	6 mm	46 cm	10-pack	blue	MMT-941
MiniMed™ Mio™ Infusion set	SC1	6 mm	46 cm	10-pack	blue	MMT-941A
MiniMed™ Mio™ Infusion set	SC1	6 mm	46 cm	10-pack	blue	MMT-941A600
Mio®	P-CAP	6 mm	46 cm	10-pack	grey	MMT-961
MiniMed™ Mio™ Infusion set	SC1	6 mm	46 cm	10-pack	grey	MMT-961A
YpsoPump® Inset	Y-Pump	6 mm	46 cm	10-pack	grey	UL1861
Dana inset™ II	S-Pump	6 mm	46 cm	10-pack	grey	86-046-52C6
inset™ II	luer lock	6 mm	60 cm	10-pack	pink	Inner box: 100-410-52 Outer box: 100-410-02
Mio®	P-CAP	6 mm	60 cm	10-pack	pink	MMT-923
MiniMed™ Mio™ Infusion set	SC1	6 mm	60 cm	10-pack	pink	MMT-923A
MiniMed™ Mio™ Infusion set	SC1	6 mm	60 cm	10-pack	pink	MMT-923A600
inset™ II	luer lock	6 mm	60 cm	10-pack	blue	Inner box: 100-410-51 Outer box: 100-410-01
Mio®	P-CAP	6 mm	60 cm	10-pack	blue	MMT-943
Mio®	P-CAP	6 mm	60 cm	2-pack	blue	MMT-943T
MiniMed™ Mio™ Infusion set	SC1	6 mm	60 cm	10-pack	blue	MMT-943A
MiniMed™ Mio™ Infusion set	SC1	6 mm	60 cm	10-pack	blue	MMT-943A600
MiniMed™ Mio™ Infusion set	SC1	6 mm	60 cm	2-pack	blue	MMT-943AT
inset™ II	luer lock	6 mm	60 cm	10-pack	grey	Inner box: 100-410-50 Outer box: 100-410-00
inset™ II	luer lock	6 mm	60 cm	2-pack	grey	Inner box: 100-410-50 Outer box: 100-410-20
Mio®	P-CAP	6 mm	60 cm	10-pack	grey	MMT-963
MiniMed™ Mio™ Infusion set	SC1	6 mm	60 cm	10-pack	grey	MMT-963A
AutoSoft90™	t:lock	6 mm	60 cm	10-pack	pink	1002821
AutoSoft90™	t:lock	6 mm	60 cm	10-pack	blue	1002823
AutoSoft90™	t:lock	6 mm	60 cm	10-pack	grey	1002817
AutoSoft90™	t:lock	6 mm	60 cm	2-pack	grey	1000281
YpsoPump® Inset	Y-Pump	6 mm	60 cm	10-pack	grey	UL2461

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On behalf of the President
Béatrice LYS
Technical Director

Commercial reference	Technical product description					Item#
	connector	cannula	tubing	packaging	color	
Dana inset™ II	S-Pump	6 mm	60 cm	10-pack	grey	86-060-52C6
Mio®	P-CAP	6 mm	80 cm	10-pack	pink	MMT-925
MiniMed™ Mio™ Infusion set	SC1	6 mm	80 cm	10-pack	pink	MMT-925A
MiniMed™ Mio™ Infusion set	SC1	6 mm	80 cm	10-pack	pink	MMT-925A600
Mio®	P-CAP	6 mm	80 cm	10-pack	blue	MMT-945
MiniMed™ Mio™ Infusion set	SC1	6 mm	80 cm	10-pack	blue	MMT-945A
MiniMed™ Mio™ Infusion set	SC1	6 mm	80 cm	10-pack	blue	MMT-945A600
Mio®	P-CAP	6 mm	80 cm	10-pack	grey	MMT-965
MiniMed™ Mio™ Infusion set	SC1	6 mm	80 cm	10-pack	grey	MMT-965A
MiniMed™ Mio™ Infusion set	SC1	6 mm	80 cm	10-pack	grey	MMT-965A600
MiniMed™ Mio™ Infusion set	SC1	9 mm	80 cm	2-pack	grey	MMT-975AT
YpsoPump® Inset	Y-Pump	6 mm	80 cm	10-pack	grey	UL3161
Dana inset™ II	S-Pump	6 mm	80 cm	10-pack	grey	86-080-52C6
inset™ II	luer lock	6 mm	110 cm	10-pack	grey	Inner box: 100-412-50 Outer box: 100-412-00
AutoSoft90™	t:lock	6 mm	110 cm	10-pack	grey	1002818
YpsoPump® Inset	Y-Pump	6 mm	110 cm	10-pack	grey	UL4361
Dana inset™ II	S-Pump	6 mm	110 cm	10-pack	grey	86-110-52C6
YpsoPump® Inset	Y-Pump	9 mm	46 cm	10-pack	grey	UL1891
Dana inset™ II	S-Pump	9 mm	46 cm	10-pack	grey	86-046-52C9
inset™ II	luer lock	9 mm	60 cm	10-pack	pink	Inner box: 100-411-52 Outer box: 100-411-02
AutoSoft90™	t:lock	9 mm	60 cm	10-pack	pink	1002822
inset™ II	luer lock	9 mm	60 cm	10-pack	blue	Inner box: 100-411-51 Outer box: 100-411-01
AutoSoft90™	t:lock	9 mm	60 cm	10-pack	blue	1002824
inset™ II	luer lock	9 mm	60 cm	10-pack	grey	Inner box: 100-411-50 Outer box: 100-411-00
inset™ II	luer lock	9 mm	60 cm	2-pack	grey	Inner box: 100-411-50 Outer box: 100-411-20
AutoSoft90™	t:lock	9 mm	60 cm	10-pack	grey	1002819
AutoSoft90™	t:lock	9 mm	60 cm	2-pack	grey	1000282
YpsoPump® Inset	Y-Pump	9 mm	60 cm	10-pack	grey	UL2491
Dana inset™ II	S-Pump	9 mm	60 cm	10-pack	grey	86-060-52C9
Mio®	P-CAP	9 mm	80 cm	10-pack	grey	MMT-975

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On behalf of the President
Béatrice LYS
Technical Director

Commercial reference	Technical product description					Item#
	connector	cannula	tubing	packaging	color	
Mio®	P-CAP	9 mm	80 cm	2-pack	grey	MMT-975T
MiniMed™ Mio™ Infusion set	SC1	9 mm	80 cm	10-pack	grey	MMT-975A
MiniMed™ Mio™ Infusion set	SC1	9 mm	80 cm	10-pack	grey	MMT-975A600
YpsoPump® Inset	Y-Pump	9 mm	80 cm	10-pack	grey	UL3191
Dana inset™ II	S-Pump	9 mm	80 cm	10-pack	grey	86-080-52C9
inset™ II	luer lock	9 mm	110 cm	10-pack	grey	Inner box: 100-413-50 Outer box: 100-413-00
AutoSoft90™	t:lock	9 mm	110 cm	10-pack	grey	1002820
YpsoPump® Inset	Y-Pump	9 mm	110 cm	10-pack	grey	UL4391
Dana inset™ II	S-Pump	9 mm	110 cm	10-pack	grey	86-110-52C9

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Béatrice LYS

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On behalf of the President
Béatrice LYS
Technical Director

Product family: DHF-15 Inset 30

Commercial reference	Technical product description					Item#
	connector	cannula	tubing	packaging	color	
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
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
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
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
Mio™ 30	P-CAP	13 mm	60 cm	10-pack	grey	MMT-905
Mio™ 30	P-CAP	13 mm	60 cm	2-pack	grey	MMT-905T
MiniMed™ Mio™ 30 Infusion set	SC1	13 mm	60 cm	10-pack	grey	MMT-905A
MiniMed™ Mio™ 30 Infusion set	SC1	13 mm	60 cm	10-pack	grey	MMT-905A600
MiniMed™ Mio™ 30 Infusion set	SC1	13 mm	60 cm	2-pack	grey	MMT-905AT
AutoSoft30™	t:lock	13 mm	60 cm	2-pack	grey	1000283
AutoSoft30™	t:lock	13 mm	60 cm	10-pack	grey	1002825
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
Mio™ 30	P-CAP	13 mm	110 cm	10-pack	grey	MMT-906
MiniMed™ Mio™ 30 Infusion set	SC1	13 mm	110 cm	10-pack	grey	MMT-906A
MiniMed™ Mio™ 30 Infusion set	SC1	13 mm	110 cm	10-pack	grey	MMT-906A600
AutoSoft30™	t:lock	13 mm	110 cm	10-pack	grey	1002826

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Béatrice LYS
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On behalf of the President
Béatrice LYS
Technical Director

Product family: DHF-19 i-Port Advance

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

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On behalf of the President
Béatrice LYS
 Technical Director

Product family: DHF-21 neria multi

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

Product family: DHF-23 neria soft 90

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

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On behalf of the President
Béatrice LYS
Technical Director

Product family: DHF-25.1 Inset guard

Commercial reference	Technical product description					Item#
	connector	cannula	tubing	packaging	color	
neria™ guard	luer lock	6 mm	12 cm	10-pack	N/A	704012-5226
neria™ guard	luer lock	6 mm	30 cm	10-pack	N/A	704030-5226
neria™ guard	luer lock	6 mm	60 cm	10-pack	N/A	704060-5226
MiniMed™ Mio™ Advance	luer lock	6 mm	60 cm	10-pack	grey	MMT-247
MiniMed™ Mio™ Advance	luer lock	6 mm	60 cm	10-pack	grey	MMT-247600
MiniMed™ Mio™ Advance	luer lock	6 mm	60 cm	2-pack	grey	MMT-247T
MiniMed™ Mio™ Advance	P-CAP	6 mm	60 cm	10-pack	grey	MMT-242
MiniMed™ Mio™ Advance	P-CAP	6 mm	60 cm	10-pack	grey	MMT-242600
MiniMed™ Mio™ Advance	P-CAP	6 mm	60 cm	2-pack	grey	MMT-242T
MiniMed™ Mio™ Advance	SC1	6 mm	60 cm	10-pack	grey	MMT-242A
MiniMed™ Mio™ Advance	SC1	6 mm	60 cm	10-pack	grey	MMT-242A600
MiniMed™ Mio™ Advance	SC1	6 mm	60 cm	2-pack	grey	MMT-242AT

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On behalf of the President
Béatrice LYS
Technical Director

Commercial reference	Technical connector	product cannula	description tubing	packaging	color	Item#
MiniMed™ Mio™ Advance	SC1	6 mm	110 cm	10-pack	grey	MMT-213A
MiniMed™ Mio™ Advance	SC1	6 mm	110 cm	10-pack	grey	MMT-213A600
neria™ guard	luer lock	6 mm	80 cm	10-pack	N/A	704080-5226
neria™ guard	luer lock	6 mm	110 cm	10-pack	N/A	704110-5226
neria™ guard	luer lock	9 mm	12 cm	10-pack	N/A	704012-5229
neria™ guard	luer lock	9 mm	30 cm	10-pack	N/A	704030-5229
neria™ guard	luer lock	9 mm	60 cm	10-pack	N/A	704060-5229
neria™ guard	luer lock	9 mm	60 cm	2-pack	N/A	702060-5229
MiniMed™ Mio™ Advance	P-CAP	9 mm	60 cm	10-pack	grey	MMT-243
MiniMed™ Mio™ Advance	P-CAP	9 mm	60 cm	10-pack	grey	MMT-243600
MiniMed™ Mio™ Advance	SC1	9 mm	60 cm	10-pack	grey	MMT-243A
MiniMed™ Mio™ Advance	SC1	9 mm	60 cm	10-pack	grey	MMT-243A600
MiniMed™ Mio™ Advance	SC1	9 mm	60 cm	2-pack	grey	MMT-243AT
neria™ guard	luer lock	9 mm	80 cm	10-pack	N/A	704080-5229

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On behalf of the President
Béatrice LYS
Technical Director

Commercial reference	Technical connector	product cannula	description tubing	packaging	color	Item#
neria™ guard	luer lock	9 mm	80 cm	2-pack	N/A	702080-5229
neria™ guard	luer lock	9 mm	110 cm	10-pack	N/A	704110-5229
MiniMed™ Mio™ Advance	luer lock	9 mm	110 cm	10-pack	grey	MMT-248
MiniMed™ Mio™ Advance	luer lock	9 mm	110 cm	10-pack	grey	MMT-248600
MiniMed™ Mio™ Advance	P-CAP	9 mm	110 cm	10-pack	grey	MMT-244
MiniMed™ Mio™ Advance	P-CAP	9 mm	110 cm	10-pack	grey	MMT-244600
MiniMed™ Mio™ Advance	SC1	9 mm	110 cm	10-pack	grey	MMT-244A
MiniMed™ Mio™ Advance	SC1	9 mm	110 cm	10-pack	grey	MMT-244A600
neria™ guard cannula	N/A	6 mm	N/A	10-pack	N/A	704000-5226
neria™ guard cannula	N/A	9 mm	N/A	10-pack	N/A	704000-5229
Medtronic Extended	H-CAP	6 mm	46 cm	1-pack	N/A	MMT-430AJ
Medtronic Extended	H-CAP	6 mm	46 cm	3-pack	N/A	MMT-430AH
Medtronic Extended	H-CAP	6 mm	46 cm	4-pack	N/A	MMT-430AK
Medtronic Extended	H-CAP	6 mm	46 cm	4-pack	N/A	MMT-430AK600

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On behalf of the President
Béatrice LYS
Technical Director

Commercial reference	Technical connector	product cannula	description tubing	packaging	color	Item#
Medtronic Extended	H-CAP	6 mm	46 cm	5-pack	N/A	MMT-430AG
Medtronic Extended	H-CAP	6 mm	46 cm	5-pack	N/A	MMT-430AG600
Medtronic Extended	H-CAP	6 mm	46 cm	10-pack	N/A	MMT-430A
Medtronic Extended	H-CAP	6 mm	60 cm	1-pack	N/A	MMT-431AJ
Medtronic Extended	H-CAP	6 mm	60 cm	3-pack	N/A	MMT-431AH
Medtronic Extended	H-CAP	6 mm	60 cm	4-pack	N/A	MMT-431AK
Medtronic Extended	H-CAP	6 mm	60 cm	4-pack	N/A	MMT-431AK600
Medtronic Extended	H-CAP	6 mm	60 cm	5-pack	N/A	MMT-431AG
Medtronic Extended	H-CAP	6 mm	60 cm	5-pack	N/A	MMT-431AG600
Medtronic Extended	H-CAP	6 mm	60 cm	10-pack	N/A	MMT-431A
Medtronic Extended	H-CAP	6 mm	80 cm	1-pack	N/A	MMT-432AJ
Medtronic Extended	H-CAP	6 mm	80 cm	3-pack	N/A	MMT-432AH
Medtronic Extended	H-CAP	6 mm	80 cm	4-pack	N/A	MMT-432AK
Medtronic Extended	H-CAP	6 mm	80 cm	4-pack	N/A	MMT-432AK600
Medtronic Extended	H-CAP	6 mm	80 cm	5-pack	N/A	MMT-432AG
Medtronic Extended	H-CAP	6 mm	80 cm	5-pack	N/A	MMT-432AG600
Medtronic Extended	H-CAP	6 mm	80 cm	10-pack	N/A	MMT-432A

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On behalf of the President
Béatrice LYS
Technical Director

Commercial reference	Technical connector	product cannula	description tubing	packaging	color	Item#
Medtronic Extended	H-CAP	6 mm	110 cm	1-pack	N/A	MMT-433AJ
Medtronic Extended	H-CAP	6 mm	110 cm	3-pack	N/A	MMT-433AH
Medtronic Extended	H-CAP	6 mm	110cm	4-pack	N/A	MMT-433AK
Medtronic Extended	H-CAP	6 mm	110cm	4-pack	N/A	MMT-433AK600
Medtronic Extended	H-CAP	6 mm	110cm	5-pack	N/A	MMT-433AG
Medtronic Extended	H-CAP	6 mm	110cm	5-pack	N/A	MMT-433AG600
Medtronic Extended	H-CAP	6 mm	110 cm	10-pack	N/A	MMT-433A
Medtronic Extended	H-CAP	9 mm	46 cm	1-pack	N/A	MMT-440AJ
Medtronic Extended	H-CAP	9 mm	46 cm	3-pack	N/A	MMT-440AH
Medtronic Extended	H-CAP	9 mm	46 cm	4-pack	N/A	MMT-440AK
Medtronic Extended	H-CAP	9 mm	46 cm	4-pack	N/A	MMT-440AK600
Medtronic Extended	H-CAP	9 mm	46 cm	5-pack	N/A	MMT-440AG
Medtronic Extended	H-CAP	9 mm	46 cm	5-pack	N/A	MMT-440AG600
Medtronic Extended	H-CAP	9 mm	46 cm	10-pack	N/A	MMT-440A
Medtronic Extended	H-CAP	9 mm	60 cm	1-pack	N/A	MMT-441AJ
Medtronic Extended	H-CAP	9 mm	60 cm	3-pack	N/A	MMT-441AH
Medtronic Extended	H-CAP	9 mm	60 cm	4-pack	N/A	MMT-441AK

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On behalf of the President
Béatrice LYS
Technical Director

Commercial reference	Technical connector	product cannula	description tubing	packaging	color	Item#
Medtronic Extended	H-CAP	9 mm	60 cm	4-pack	N/A	MMT-441AK600
Medtronic Extended	H-CAP	9 mm	60 cm	5-pack	N/A	MMT-441AG
Medtronic Extended	H-CAP	9 mm	60 cm	5-pack	N/A	MMT-441AG600
Medtronic Extended	H-CAP	9 mm	60 cm	10-pack	N/A	MMT-441A
Medtronic Extended	H-CAP	9 mm	80 cm	1-pack	N/A	MMT-442AJ
Medtronic Extended	H-CAP	9 mm	80 cm	3-pack	N/A	MMT-442AH
Medtronic Extended	H-CAP	9 mm	80 cm	4-pack	N/A	MMT-442AK
Medtronic Extended	H-CAP	9 mm	80 cm	4-pack	N/A	MMT-442AK600
Medtronic Extended	H-CAP	9 mm	80 cm	5-pack	N/A	MMT-442AG
Medtronic Extended	H-CAP	9 mm	80 cm	5-pack	N/A	MMT-442AG600
Medtronic Extended	H-CAP	9 mm	80 cm	10-pack	N/A	MMT-442A
Medtronic Extended	H-CAP	9 mm	110 cm	1-pack	N/A	MMT-443AJ
Medtronic Extended	H-CAP	9 mm	110 cm	3-pack	N/A	MMT-443AH
Medtronic Extended	H-CAP	9 mm	110cm	4-pack	N/A	MMT-443AK
Medtronic Extended	H-CAP	9 mm	110cm	4-pack	N/A	MMT-443AK600
Medtronic Extended	H-CAP	9 mm	110cm	5-pack	N/A	MMT-443AG
Medtronic Extended	H-CAP	9 mm	110cm	5-pack	N/A	MMT-443AG600
Medtronic Extended	H-CAP	9 mm	110 cm	10-pack	N/A	MMT-443A

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On behalf of the President
Béatrice LYS
Technical Director

Sites couverts et Activités / Locations and Activities

Sites / Locations	Activités / Activities
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

Modifications / Modifications

Identification des modifications apportées au certificat CE n° 9559 rev. 32 :

Identification of the modifications made to the CE certificate n° 9559 rev. 32:

Modifications / Modifications	Dossier(s) / File(s) N°	Date / Date
Mise à jour de la liste des références Update of list of references	P602289	05/09/2022 09/05/2022
Nouvelle référence de rapport dans le cadre du maintien de la certification New file reference in the framework of the maintenance of the certification	P607545	20/11/2023 11/20/2023
Mise à jour de la liste des références Update of list of references	P607545_P6	29/01/2024 01/29/2024

GMED 0459

GMED - 37058 rev. 6
Modifie le document n° 37058 rev. 5



On behalf of the President
Béatrice LYS
Technical Director