GUVERNUL REPUBLICII MOLDOVA

SERVICIUL FISCAL DE STAT

MCabinet
PORTALUL GUVERNAMENTAL AL CETĂȚEANULUI ȘI AL UNITĂȚILOR DE DREPT

CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr. № **1431280**

Din От **04.03.2025 14:31**

DATE DESPRE CONTRIBUABIL / ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal / Numărul de identificare
Фискальный код / Идентификационный номер

1007600044280

Denumirea
Наименование

Societatea Comercială OXIVIT-MED S.R.L.

ATESTAREA LIPSEI SAU EXISTENȚEI RESTANȚELOR CONFORM DATELOR SISTEMULUI INFORMAȚIONAL AUTOMATIZAT / ПОДТВЕРЖДЕНИЕ ОТСУТСВИЯ ИЛИ НАЛИЧИЯ ЗАДОЛЖНОСТЕЙ СОГЛАСНО ДАННЫМ ИНФОРМАЦИОННОЙ АВТОМАТИЗИРОВАННОЙ СИСТЕМЫ

La data emiterii prezentului certificat restanța față de bugetul public național constituie
На дату выдачи данной справки задолжность перед национальном публичным бюджетом составляет

0 MDL

VALABIL PÂNĂ LA / ДЕЙСТВИТЕЛЕН ДО **19.03.2025 14:31**

Prezentul document este eliberat în temeiul Art. 29, alin. (3) din Legea cu privire la registre nr. 71/2007 și în baza datelor furnizate de Serviciul Fiscal de Stat în Portalul Guvernamental al Cetățeanului și al Unităților de Drept / Справка выдана в соответсвие со ст. 29 п. (3) Закона о реестрах № 71/2007 на основании данных, предостоставленных Государственной налоговой службой на Портале Правительства Гражданина и Юридических Лиц.

Generat și semnat de Portalul Guvernamental al Cetățeanului și al Unităților de Drept la **04.03.2025 14:31**

Prezentul certificat este semnat electronic în conformitate cu Legea nr.124 din 19.05.2022
Сертификат подписан электронной попдписью в соответсвие с Законом № 124 от 19.05.2022

Certificatul este descărcat din Portalul Guvernamental al Cetățeanului și al Unităților de Drept (mcabinet.gov.md) și este semnat electronic de către posesorul acestui portal și are aceiași valoare juridică ca și documentele eliberate pe suport de hârtie de către organele cu atribuții de administrare fiscală. Verificarea autenticității semnăturii electronice poate fi realizată cu ajutorul Serviciului Guvernamental de Semnătură Electronică (msign.gov.md)

Сертификат скачен с Правительственного Портала Гражданина и Юридических Лиц (mcabinet.gov.md) и подписан электронной подписью владельца портала и имеет такаю же юридическую силу, как и документы выдаваемые на бумаге органами налоговой администрации. Проверку подлинности электронной подписи можно осуществить с помощью Государсвенной Службой Электронной Подписью (msign.gov.md)

Digitally signed by Kojevnikov Dmitrii
Date: 2025.03.10 11:57:01 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

MOBIAS BANCA

Nr. 12101-304

18.03.2016

CERTIFICAT
PRIVIND EXISTENTA CONTURILOR CURENTE

Prin prezentul, **BC „Mobiasbancă – Groupe Societe Generale" S.A.**, codul băncii (BIC): **MOBBMD22**, confirmă că compania **OXIVIT-MED SRL**, cod fiscal (IDNO) **1007600044280,** deține următoarele conturi curente la BC "Mobiasbancă-Groupe Societe Generale" S.A., Filiala. 1 Stejaur :

1. **MDL - 2224710SV23488147100; IBAN- MD09MO2224ASV23488147100**
2. **EUR - 2224710SV22227957100; IBAN- MD17MO2224ASV22227957100**
3. **USD - 2224710SV22214937100; IBAN- MD86MO2224ASV22214937100**

Certificatul este emis în baza cererii întreprinderii: Oxivit-Med SRL.

L.Ș.

Dumitru Popa
Director filială „Stejaur"

Executor : Mariana Guzun
Tel: 022 812 614

Filiala Nr. 1 „Stejaur"
Bd. Ştefan cel Mare şi Sfânt 196
MD-2004, Chişinău, Moldova
Cod MOBBMD22
Cont de corespondenţă 35213892
la Centrul de Decontări al BNM

Tel. +373 22 81 26 15
Fax. +373 22 81 26 15
www.mobiasbanca.md

BC „Mobiasbancă – Groupe Société Générale" SA
Capital Social: 100 000 000 MDL
Număr de înregistrare de stat - 1002600006089
Sediul Central:
bd. Ştefan cel Mare şi Sfânt 81a
MD-2012, Chişinău, Moldova

GROUPE SOCIETE GENERALE

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea Comercială "OXIVIT-MED" S.R.L.

ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal

1007600044280

Data înregistrării **30.07.2007**

Data eliberării **30.07.2007**

Bordeianu Tatiana, registrator de stat

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

CAMERA ÎNREGISTRĂRII DE STAT A REPUBLICII MOLDOVA L.Ș.

MD 0067985

AGENŢIA SERVICII PUBLICE

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

Nr. **531861** data **19.09.2023**

Denumirea completă: **Societatea Comercială "OXIVIT-MED" S.R.L.**
Denumirea prescurtată: **S.C. "OXIVIT-MED" S.R.L.**
Forma juridică de organizare: **Societate cu răspundere limitată,**
Numărul de identificare de stat şi codul fiscal (IDNO): **1007600044280**
Data înregistrării de stat: **30.07.2007**
Sediul: **MD-2032, bd . Decebal, 82, ap.(of.) 90, mun. Chişinău, Republica Moldova.**
Obiectul principal de activitate:
1. Fabricarea, comercializarea, asistenţa tehnică, repararea şi verificarea articolelor de tehnică şi optică medicală
2. Comerţul cu ridicata al parfumurilor şi produselor cosmetice
3. Comerţul cu amănuntul al produselor cosmetice şi de parfumerie, articolelor de toaletă
4. Intermedieri pentru vînzarea unui asortiment larg de mărfuri
5. Alte tipuri de comerţ cu amănuntul în magazine nespecializate
6. Alte tipuri de comerţ cu ridicata
7. Închirierea altor maşini şi echipamente

Capitalul social: **5400** lei,

Administrator: **KOJEVNIKOV DMITRII, IDNP 0972305012362,**

Asociaţii:
1. KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 5400 lei, ce constituie 100%
Beneficiar efectiv:
1.1. KOJEVNIKOV DMITRII, IDNP 0972305012362

Prezentul extras este eliberat în temeiul art.34 al Legii nr.220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: **19.09.2023**.

Registrator în domeniul înregistrării de stat **Rusu Diana**

Digitally signed by Rusu Diana
Date: 2023.09.19 11:22:47 EEST
Reason: MoldSign Signature
Location: Moldova

EB 0461498

Date cu caracter personal

c/f: 1007600044280; adresa: str. Decebal 82-90, or. Chișinău, Republica Moldova
telefon: + 373 22 808002; fax: + 373 22 808003
web: www.oxivit-med.com; e-mail:info@oxivit-med.com

Lista fondatorilor companiei SRL „Oxivit-Med”

Nr.	Numele, Prenumele	Codul Personal
1	Kojevnikov Dmitrii	0972305012362

Rev	CO#	Description of Change
1A	CO10032121	Introduce new EU Declaration of Conformity specific to RSCP Cannulae
1B	CO10054100	Update Certificate Number
1C	CO10065374	Update Cover sheet QS Certificate Applied Standards Reference
1D	CO10085461	Update model descriptions for consistency with Technical File. Update Applied Standard reference.
1E	CO10132818	Update Quality Systems Certificate number and header format
1F	CO10219507	Update certificate numbers from G1 14 11 39709 952 to G1 16 08 39709 01060 Added Design Facility address Updated Manufacturer and Notified body addresses to align with address format on certificate Updated Conformity Assessment Route Added "Class" column to attachment A to align with template per SOP31347 Updated company logo on letterhead Updated footnote on pages 2 onward to add Document and revision number
1G	RCH00027815	Created on new DoC template, updated standard number to ISO 13485:2016 and reference to applied standards.
AA	RCH00060389	Update EC Quality System Certificate from G1 16 08 39709 01060 to G1 039709 1263 Rev. 00 Update Manufacturer address Update template Minor formatting changes
AB	RCH00079603	Update EC Quality Certificate from G1 039709 1263 Rev. 00 to G1 039709 1304 Rev. 00 Clarifications to numerous device descriptions to better match product labeling.
AC	RCH00085135	Removed obsolete CFNs: 94015, 94113, 94215, 94113TD, 94115, 94115NPL, 94315, and 94415.

EC DECLARATION OF CONFORMITY

Manufacturer:	Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN 55432 USA
EC Representative	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen THE NETHERLANDS
Design Facility:	Medtronic Perfusion Systems 7611 Northland Drive, Minneapolis, MN 55428, USA
Product:	**Attachment A**
Classification, Rules:	Class IIa, Rule 7
Conformity Assessment Route	Annex II (excluding section 4)

I, the undersigned, hereby declare that the Medical Devices specified above and provided with the CE marking, meet the provisions of Council Directive 93/42/EEC of 14 June 1993 as amended by 2007/47/EC which apply to them. This declaration is supported by the Certificates according to the provisions of relevant Annex of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Standards Applied:	See **Attachment B**
Notified Body:	TÜV SÜD Product Service GmbH Zertifizierstelle Ridlerstraße 65 80339 München GERMANY
Identification Number:	0123
EC Quality System Certificate:	G1 039709 1304 Rev. 00
Place of Issue:	Minneapolis, Minnesota USA
Authorized Signature:	30 JULY 2020

Name: Michael Green
Title: Senior Manager, Regulatory Affairs

Attachment A to Declaration of Conformity DC1084

This attachment specifies the RCSP Cannulae products included in the above referenced Declaration of Conformity.

A.) Gundry Silicone RSCP with Manual Inflate Cuff
B.) DLP Silicone RCSP with Manual Inflate Cuff
C.) DLP Silicone RCSP with Auto-Inflate Cuff
D.) DLP PVC RCSP with Auto-Inflate Cuff
E.) MiRSCP

A) Gundry Silicone RCSP with Manual Inflate Cuff

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
Gundry® 10 Fr Retrograde Cannula – Manual Inflate – Silicone Body	94110	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
Gundry® 13 Fr. Retrograde Cannula – Manual-Inflate – Silicone Body	94113T	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
Gundry® 15 Fr. Retrograde Cannula – Manual-Inflate – Silicone Body	94115T	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
Gundry® 15 Fr. Retrograde Cannula – Manual-Inflate – Silicone Body	94615	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
Gundry® 15 Fr. Retrograde Cannula – Manual-Inflate – Silicone Body	94715	IIa	NA	Rule 7	G1 039709 1304 Rev. 00

B) DLP Silicone RCSP with Manual Inflate Cuff

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
DLP® 6 Fr. Retrograde Cannula – Manual-Inflate – Silicone Body	94006	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
DLP® 10 Fr. Retrograde Cannula – Manual-Inflate – Silicone Body	94010	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
DLP® 6 Fr. Retrograde Cannula – Manual-Inflate – Silicone Body	94106	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
DLP® 15 Fr. Retrograde Cannula – Manual-Inflate – Silicone Body	94215T	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
DLP® 15 Fr. Retrograde Cannula – Manual-Inflate – Silicone Body	94515	IIa	N/A	Rule 7	G1 039709 1304 Rev. 00
DLP® 15 Fr. Retrograde Cannula – Manual-Inflate – Silicone Body	94525	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
DLP® 15 Fr. Retrograde Cannula – Manual-Inflate – Silicone Body	94625	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
DLP® 15 Fr. Retrograde Cannula – Manual-Inflate – Silicone Body	94665	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
DLP® 15 Fr. Retrograde Cannula – Manual-Inflate – Silicone Body	94725	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
DLP® 15 Fr. Retrograde Cannula – Manual-Inflate – Silicone Body	94725NPL	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
DLP® 13 Fr. Retrograde Cannula – Manual-Inflate – Silicone Body	94913	IIa	94913L	Rule 7	G1 039709 1304 Rev. 00
DLP® 13 Fr. Retrograde Cannula – Manual-Inflate – Silicone Body	94913L	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
DLP® 15 Fr. Retrograde Cannula – Manual-Inflate – Silicone Body	94915	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
DLP® 15 Fr. Retrograde Cannula – Manual-Inflate – Silicone Body	94965	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
DLP® 15 Fr. Retrograde Cannula – Manual-Inflate – Silicone Body	94975	IIa	NA	Rule 7	G1 039709 1304 Rev. 00

C) DLP Silicone RCSP with Auto-Inflate Cuff

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
DLP® 15 Fr. Retrograde Cannula – Auto-Inflate – Silicone Body	94315T	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
DLP® 15 Fr. Retrograde Cannula – Auto-Inflate – Silicone Body	94415T	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
DLP® 15 Fr. Retrograde Cannula – Auto-Inflate – Silicone Body	94735	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
DLP® 15 Fr. Retrograde Cannula – Auto-Inflate – Silicone Body	94745	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
DLP® 15 Fr. Retrograde Cannula – Auto-Inflate – Silicone Body	94985	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
DLP® 15 Fr. Retrograde Cannula – Auto-Inflate – Silicone Body	94995	IIa	NA	Rule 7	G1 039709 1304 Rev. 00

D) DLP PVC RCSP with Auto-Inflate Cuff

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
DLP® 13 Fr. Retrograde Cannula – Auto-Inflate – PVC Body	94523	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
DLP® 13 Fr. Retrograde Cannula – Auto-Inflate – PVC Body	94533	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
DLP® 15 Fr. Retrograde Cannula – Auto-Inflate – PVC Body	94535	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
DLP® 15 Fr. Retrograde Cannula – Auto-Inflate – PVC Body	94535NPL	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
DLP® 15 Fr. Retrograde Cannula – Auto-Inflate – PVC Body	94835	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
DLP® 15 Fr. Retrograde Cannula – Auto-Inflate – PVC Body	94845	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
DLP® 15 Fr. Retrograde Cannula – Auto-Inflate – PVC Body	94885	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
DLP® 15 Fr. Retrograde Cannula – Auto-Inflate – PVC Body	94885K	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
DLP® 15 Fr. Retrograde Cannula – Auto-Inflate – PVC Body	94895	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
DLP® 15 Fr. Retrograde Cannula – Auto-Inflate – PVC Body	94935	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
DLP® 15 Fr. Retrograde Cannula – Auto-Inflate – PVC Body	94945	IIa	NA	Rule 7	G1 039709 1304 Rev. 00

E) MiRSCP

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
MiRCSP™ 13 Fr. Manual-Inflate Cannula with Silicone Body and Tip Deflecting Introducer	94113TDT	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
MiRCSP™ 13 Fr. Auto-Inflate Cannula with PVC Body and Tip Deflecting Introducer	94533TD	IIa	NA	Rule 7	G1 039709 1304 Rev. 00
MiRCSP™ 13 Fr. Auto-Inflate Cannula with PVC Body and Tip Deflecting Introducer	94533TDT	IIa	NA	Rule 7	G1 039709 1304 Rev. 00

Attachment B to the Declaration of Conformity DC1084: Applicable Standards

The below mentioned Standards apply to all the product(s) mentioned on the applicable CE Mark certificate.

Standard Number	Description
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes.

Refer to TF-0084, for applied standards.

Rev	CO#	Description of Change
1A	CO10032877	Introduce new EU Declaration of Conformity specific to uncoated and coated Femoral Cannulae
1B	CO10069170	Updated cover page, header, and footer to current format; Updated Quality Certificate and Product Certificate numbers, changed signatory to Sue Fidler (Senior Manager, Regulatory Affairs); Updated ISO 13485 to current standard; Updated referenced Annexes for Conformity Assessment Routes; Updated Council Directive referenced on page 2; Updated Carmeda-Coated models for DLP® Femoral Cannula and Insertion Kits; Added Trademarks; Revised product descriptions and models within families
1C	CO10121725	Addition of Next Generation Adult Cannulae and Next Generation Pediatric Cannulae
1D	CO10133707	Update Quality Systems Certificate Number and Header Format
1E	CO10134312	Correction to reflect correct model numbers for the uncoated Bio-Medicus Multistage Femoral Venous Cannula Family.
1F	CO10143817	Addition of new NG Bio-Medicus insertion kit models 96551, 96552 and 96553
1G	CO10165592	Update Declaration of Conformity to reflect new EC Quality System Certificate number Update Declaration of Conformity to reflect new EC Design Examination Certificate numbers, Added Cortiva branded device names Add classification Rule 17 for all Carmeda and Cortiva products Update Manufacturer information Update EC Representative Information Update to Notified Body information Removal of models Correction to Declaration statement Addition of new NG Bio-Medicus Adult Cannula kit models 96530, 96600

1H	CO10219507	Updated certificate numbers from G1 14 11 39709 952 to G1 16 08 39709 01060 throughout document Updated addresses to align with certificates Deleted Vention as a manufacturer Added column "Class" to attachment A, to align with template per SOP31347 Updated statement below "Conformity Assessment Route" section to align with template per SOP31347 Updated device descriptions and family names on Attachment A\ Corrected the model numbers for the "Next Generation Bio-Medicus Adult Arterial/Internal Jugular Cannula Kits", from 96350-XXX to 96530-XXX Removed model 96530-023 from attachment A number 7. Model does not exist. Rearranged device groupings on Attachment A number 8, to match family arrangement on TF-0085. Segregated models 96551, 96552, and 96553 into a separate group (Attachment A, number 15) to match TF-0085. Models do not belong to family number 10. Re-numbered subsequent families accordingly. Added Rule 7 to classification rules for Class III devices
1J	CO10227028	Remove obsolete model
AA	RCH00029491	Update to reflect design change for NG-Biomedicus dilator from B. Braun to Medcomp
AB	RCH00027815	Created on new DoC template, removed references to Carmeda, updated standard number to ISO 13485:2016 and reference to applied standards.
AC	RCH00060389	Update EC Quality System Certificate from G1 16 08 39709 01060 to G1 039709 1263 Rev. 00 Update manufacturer address Update the template and minor formatting change Updated declaration to remove obsolete models: CB57417, CB58624, CB58633, CB58729, CB58733 and CB98805-110
AD	RCH00073666	Updated EC Quality System Certificates G1 15 09 39709 992 with G1 039709 1318 Rev. 00, updated G1 039709 1263 Rev. 00 with G1 039709 1304 Rev. 00 and updated EC Design Examination Certificate(s) G7 15 12 39709 01017 with G7 039709 1017 Rev. 01

EC DECLARATION OF CONFORMITY

Manufacturer:	Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN 55432 USA
EC Representative	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen THE NETHERLANDS
Design Facility:	Medtronic Perfusion Systems 7611 Northland Drive Minneapolis, MN 55428 USA
Manufacturing Facility	Medtronic Mexico S.de R.L. de CV Av. Paseo Cucapah 10510 El Lago, C.P.22210 Tijuana, Baja California, MEXICO
Product:	See **Attachment A**
Classification, Rules:	Class IIa, Rule 7 (Uncoated models) Class III, Rule 7, 13 & 17 (Cortiva™ Coated models)
Conformity Assessment Route	Annex II, excluding section (4) (for Class IIa) Annex II, including section (4) (for Class III)

I, the undersigned, hereby declare that the Medical Devices specified above and provided with the CE marking, meet the provisions of Council Directive 93/42/EEC of 14 June 1993 as amended by 2007/47/EC which apply to them. This declaration is supported by the Certificates according to the provisions of relevant Annex of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Standards Applied: See **Attachment B**

Title: Declaration of Conformity: Femoral Cannulae

Notified Body:	TÜV SÜD Product Service GmbH Zertifizierstelle Ridlerstraße 65 80339 München GERMANY
Identification Number:	0123
EC Quality System Certificate:	G1 039709 1304 REV. 00(Uncoated products) G1 039709 1318 REV. 00 (Cortiva™ Coated Products)
EC Design Examination Certificate(s):	G7 039709 1017 REV. 01 (Cortiva™ Coated Products)
Place of Issue:	Minneapolis, Minnesota USA

Authorized Signature:

Name: Michael Green
Title: Senior. Manager, Regulatory Affairs
Date: 05 JUNE 2020

Attachment A to Declaration of Conformity DC1085

This attachment specifies the uncoated and Cortiva coated products included in the above referenced Declaration of Conformity. The following is an outline of the list of products presented in each section of this attachment:

Uncoated Products

1. DLP® Femoral Arterial Cannulae
2. DLP® Femoral Venous Cannulae
3. DLP® Femoral Venous Cannulae with Guidewire
4. Carpentier Bi-Caval Femoral Venous Cannulae
5. Bio-Medicus® One Piece Femoral Venous Cannulae
6. Bio-Medicus® One Piece Femoral Cannulae Kits
7. Bio-Medicus® One Piece Femoral Arterial Cannulae
8. Bio-Medicus® Multi-Stage Femoral Venous Cannulae
9. Bio-Medicus™ Adult Cannula and Introducer
10. Bio-Medicus™ Adult Venous Cannula and Introducer
11. Bio-Medicus™ Pediatric Arterial Cannula and Introducer
12. Bio-Medicus™ Pediatric Venous Cannula and Introducer
13. Bio-Medicus™ Insertion Kit
14. Bio-Medicus™ Adult Arterial/Internal Jugular Cannula Kit
15. Bio-Medicus™ Adult Venous Cannula Kit

Cortiva™ Coated Products

16. DLP™ Femoral Arterial Cannulae
17. Carpentier Bi-Caval Femoral Venous Cannulae
18. Bio-Medicus™ Pediatric Femoral Venous Cannulae and Obturator
19. Bio-Medicus™ Femoral Venous Cannulae Kits
20. Bio-Medicus™ Femora Venous Cannulae and Introducer
21. Bio-Medicus™ Pediatric Cannulae
22. Bio-Medicus™ Femoral Arterial Canhulae Kits
23. Bio-Medicus™ Pediatric Femoral Arterial Cannulae and Obturator
24. Bio-Medicus™ Femoral Arterial Cannulae and Introducer

1. DLP® Femoral Arterial Cannulae

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
17.8 cm (7 in) overall length, 0.95 cm (3/8 in) vented connector	57414	IIa	57417 57421	7	G1 039709 1304 REV. 00

2. DLP® Femoral Venous Cannulae

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
53.3 cm (21 in) overall length, 0.95 cm (3/8 in) non-vented connector	58517	IIa	58521	7	G1 039709 1304 REV. 00

3. DLP® Femoral Venous Cannulae with Guidewire

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
64.8 cm (25.5 in) overall length, 0.95 cm (3/8 in) connection site, guidewire	96328	IIa	NA	7	G1 039709 1304 REV. 00
64.8 cm (25.5 in) overall length, 0.95 cm (3/8 in) non-vented connector, guidewire	96428	IIa	NA	7	G1 039709 1304 REV. 00

4. Carpentier Bi-Caval Femoral Venous Cannulae

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
With 1.27 cm (½ in) non-vented connector 24/29Fr.	58729	IIa	58733	7	G1 039709 1304 REV. 00

5. Bio-Medicus® One Piece Femoral Venous Cannula

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
Pediatric 19 cm (7.5 in) overall length, 0.64 cm (1/4 in) non-vented connector	96830-XXX	IIa	96830-008 96830-010 96830-012 96830-014	7	G1 039709 1304 REV. 00
76.2 cm (30 in) overall length, 0.95 cm (3/8 in) non-vented connector	96670-XXX	IIa	96670-015 96670-017 96670-019 96670-021	7	G1 039709 1304 REV. 00
76.2 cm (30 in) overall length, 1.27 cm (1/2 in) non-vented connector	96370-XXX	IIa	96370-023 96370-025 96370-027 96370-029	7	G1 039709 1304 REV. 00
Pediatric Venous Cannula and Obturator, 14 Fr x 10cm, ¼ x ¼ LL Connector	98800-115	IIa	NA	7	G1 039709 1304 REV. 00
Percutaneous kit, Adult Femoral, 23Fr x 38cm, 3.8x3/8 Connector	98000-155	IIa	NA	7	G1 039709 1304 REV. 00

6. Bio-Medicus® One Piece Femoral Cannula Kits

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
76.2 cm (30 in) overall length venous, 0.95 cm (3/8 in) non-vented connector	96600-XXX	IIa	96600-015 96600-017 96600-019 96600-021 96600-023	7	G1 039709 1304 REV. 00
43.2 cm (17 in) overall length arterial, 0.95 (3/8 in) vented connector	96530-XXX	IIa	96530-015 96530-017 96530-019 96530-021	7	G1 039709 1304 REV. 00
43.2 cm (17 in) overall length arterial, 1.27 cm (1/2 in) non-vented connector with radiopaque marker, no hemostasis cap	96540-023	IIa	NA	7	G1 039709 1304 REV. 00

7. Bio-Medicus® One Piece Femoral Arterial Cannula

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
Pediatric19 cm (7.5 in) overall length, 0.64 cm (1/4 in) non-vented connector	96820-XXX	IIa	96820-008 96820-010 96820-012 96820-014	7	G1 039709 1304 REV. 00
43.2 cm (17 in) overall length, 0.95 (3/8 in) vented connector	96570-XXX	IIa	96570-015 96570-017 96570-019 96570-021	7	G1 039709 1304 REV. 00
Femoral Arterial Cannula and introducer	98000-XXX	IIa	98000-105 98000-106 98000-228	7	G1 039709 1304 REV. 00
Pediatric Arterial Cannula and Obturator	98800-XXX	IIa	98800-108 98800-109 98800-110 98800-126 98800-128 98800-130 98800-131 98800-142 98800-143	7	G1 039709 1304 REV. 00

8. Bio-Medicus® Multi-Stage Femoral Venous Cannula

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
Bio-Medicus™ Multistage Femoral Venous Cannulae with Percutaneous Kit; 76.2 cm (30 in) overall length, 0.95 cm (3/8 in) non-vented connector	96880-XXX	IIa	96880-019 96880-021 96880-025	7	G1 039709 1304 REV. 00

9. Bio-Medicus™ Adult Cannula and Introducer

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
Bio-Medicus™ Adult Cannula and Introducer	96570-xxx	IIa	96570-115 96570-117 96570-119 96570-121 96570-123 96570-125	7	G1 039709 1304 REV. 00

10. Bio-Medicus™ Adult Venous Cannula and Introducer

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
Bio-Medicus™ Adult Venous Cannula and Introducer	96670-xxx	IIa	96670-115 96670-117 96670-119 96670-121 96670-123 96670-125 96670-127 96670-129	7	G1 039709 1304 REV. 00

11. Bio-Medicus™ Pediatric Arterial Cannula and Introducer

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
Bio-Medicus™ Pediatric Arterial Cannula and Introducers	96820-xxx	IIa	96820-108 96820-110 96820-112 96820-114	7	G1 039709 1304 REV. 00

12. Bio-Medicus™ Pediatric Venous Cannula and Introducer

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
Bio-Medicus™ Pediatric Venous Cannula and Introducer	96830-xxx	IIa	96830-108 96830-110 96830-112 96830-114	7	G1 039709 1304 REV. 00

13. Bio-Medicus™ Insertion Kit

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
Bio-Medicus™ Venous Insertion Kit	96551	IIa	NA	7	G1 039709 1304 REV. 00
Bio-Medicus™ Insertion Kit	96552	IIa	NA	7	G1 039709 1304 REV. 00
Bio-Medicus™ Pediatric Insertion Kit	96553	IIa	NA	7	G1 039709 1304 REV. 00

14. Bio-Medicus™ Adult Arterial/Internal Jugular Cannula Kit

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
Bio-Medicus™ Adult Cannula Kit	96530-xxx	IIa	96530-115 96530-117 96530-119 96530-121 96530-123 96530-125	7	G1 039709 1304 REV. 00

15. Bio-Medicus™ Adult Venous Cannula Kit

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
Bio-Medicus™ Adult Venous Cannula Kit	96600-xxx	IIa	96600-115 96600-117 96600-119 96600-121 96600-123 96600-125 96600-127 96600-129	7	G1 039709 1304 REV. 00

16. DLP™ Femoral Arterial Cannulae with Cortiva™ BioActive Surface

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
DLP™ Femoral Arterial Cannulae with Cortiva™ BioActive Surface	CB57421	NA	CB57417 CB57421	7, 13, 17	G7 039709 1017 REV. 01

17. Bio-Medicus™ Pediatric Femoral Venous Cannulae and Obturator with Cortiva™ BioActive Surface

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
Bio-Medicus™ Pediatric Femoral Venous Cannulae and Obturator with Cortiva™ BioActive Surface	CB96835-xxx	III	CB96835-008 CB96835-010 CB96835-012 CB96835-014	7, 13, 17	G7 039709 1017 REV. 01

18. Bio-Medicus™ Femoral Venous Cannulae Kits with Carmeda®/Cortiva™ BioActive Surface

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
Bio-Medicus™ Femoral Venous Cannulae Kits with Cortiva™ BioActive Surface	CB96605-xxx CB98805-xxx	III	CB96605-015 CB96605-017 CB96605-019 CB96605-021 CB96605-023 CB98805-104 CB98805-105 CB98805-106	7, 13, 17	G7 039709 1017 REV. 01

19. Bio-Medicus™ Femora Venous Cannulae and Introducer with Cortiva™ BioActive Surface

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
Bio-Medicus™ Femoral Venous Cannulae with Cortiva™ BioActive Surface	CB96670-xxx CB96345-xxx	III	CB96670-015 CB96670-017 CB96670-019 CB96670-021 CB96345-023 CB96345-025 CB96345-027 CB96345-029	7, 13, 17	G7 039709 1017 REV. 01

20. Bio-Medicus™ Femoral Arterial Cannulae Kits with Cortiva™ BioActive Surface

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
Bio-Medicus™ Femoral Arterial Cannulae Kits with Cortiva™ BioActive Surface	CB96535-xxx CB98805-xxx	III	CB96535-015 CB96535-017 CB96535-019 CB96535-021 CB96540-023 CB98805-102 CB98805-103	7, 13, 17	G7 039709 1017 REV. 01

21. Bio-Medicus™ Pediatric Femoral Arterial Cannulae and Obturator with Cortiva™ BioActive Surface

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
Bio-Medicus™ Pediatric Femoral Arterial Cannulae and Obturator Kits with Cortiva™ BioActive Surface	CB96825-xxx	III	CB96825-008 CB96825-010 CB96825-012 CB96825-014	7, 13, 17	G7 039709 1017 REV. 01

22. Bio-Medicus™ Femoral Arterial Cannulae and Introducer with Cortiva™ BioActive Surface

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
Bio-Medicus™ Femoral Arterial Cannulae and Introducer with Cortiva™ BioActive Surface	CB96570-xxx	III	CB96570-015 CB96570-017 CB96570-019 CB96570-021	7, 13, 17	G7 039709 1017 REV. 01

Attachment B to the Declaration of Conformity DC1085: Applicable Standards

The below mentioned Standards apply to all the product(s) mentioned on the applicable CE Mark certificate.

Standard Number	Description
EN ISO 13485: 2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes.

Refer to TF-0085 and WKG-1009 for a list of applied standards

Rev	CO#	Description of Change
1A	CO10032504	Introduce new EU Declaration of Conformity specific to Tourniquet Sets
1B	CO10051805	Replace old QMS certificate number with new QMS certificate number
1C	CO10073368	Update QMS Certificate number, update QMS standard reference, remove duplicate model numbers, update signatory, update cover page, headers, and footers to current format
1D	CO10084595	Re-categorize models within the product families (no new models) for clarity on associated Instructions for Use, adding note for obsolete model 79014
1E	CO10133899	Update Quality Systems Certificate Number and Header Format
1F	CO10219234	Update certificate numbers from G1 14 11 39709 952 to G1 16 08 39709 01060. Updated addresses to align with certificates Added classification to attachment A to align with template per SOP31347 Removed information on obsolete model 79014 Updated logo on letterhead Updated products name and device description to align with the Technical File
1G	RCH00027815	Created on new DoC template, removed Manufacturing Site reference, updated standard number to ISO 13485:2016 and reference to applied standards.
AA	RCH00061981	Update EC Quality System Certificate from G1 16 08 39709 01060 to G1 039709 1263 Rev. 00 Update the template and minor formatting changes Update manufacturer address
AB	RCH00079927	Updated EC Quality System Certificate from G1 039709 1263 Rev. 00 to G1 039709 1304 Rev. 00 Clarifications to numerous device descriptions to better match product labeling.

EC DECLARATION OF CONFORMITY

Manufacturer	Medtronic Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA
EC Representative	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Design Facility	Medtronic Perfusion Systems 7611 Northland Drive Minneapolis, MN 55428 USA
Product	See **Attachment A**
Classification, Rules	Class IIa, Rule 6
Conformity Assessment Route	Annex II excluding (4)

I, the undersigned, hereby declare that the Medical Devices specified above and provided with the CE marking, meet the provisions of Council Directive 93/42/EEC of 14 June 1993 as amended by 2007/47/EC which apply to them. This declaration is supported by the Certificates according to the provisions of relevant Annex of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Standards Applied	See **Attachment B**
Notified Body	TÜV SÜD Product Service GmbH Zertifizierstelle Ridlerstraße 65 80339 München GERMANY
Identification Number	0123
EC Quality System Certificate	G1 039709 1304 Rev. 00
Place of Issue:	Minneapolis, Minnesota USA

Authorized Signature:

Name: Michael Green
Title: Senior Manager, Regulatory Affairs
Date: 22 MAY 2020

Attachment A to Declaration of Conformity DC1130

This attachment specifies the Class IIa products included in the above referenced Declaration of Conformity.

A.) DLP® Tube-Style Tourniquet Sets

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
DLP® 5.5 in (14.0 cm) Tourniquet Kit	79003	IIa	79004 79006 79015 79016 79019 79022 79023 79026 79027	6	G1 039709 1304 Rev. 00

B.) Tournikwik Style Tourniquet Sets

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
TourniKwik™ 6 in (15.2 cm) Tourniquet Kit	79010	IIa	79011 79012 79013 79014*	6	G1 039709 1304 Rev. 00

C.) Sure-Snare Style Tourniquets

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
Sure-Snare™ 7.5 in (19.1 cm) Tourniquet Kit	79008	IIa	79020	6	G1 039709 1304 Rev. 00

D.) DLP® Vena Cava and Tube-Style Tourniquet Sets

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
DLP® 7 in (17.8 cm) Tourniquet Kit	79005	IIa	79009	6	G1 039709 1304 Rev. 00

Attachment B to the Declaration of Conformity DC1130: Applicable Standards

The below mentioned Standards apply to all the product(s) mentioned on the applicable CE Mark certificate.

Standard Number	Description
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes.

Refer to TF-0130 for a list of applied standards.

Rev	CO#	Description of Change
1A	CO10042078	Introduce new EU Declaration of Conformity specific to uncoated and coated Arterial Cannulae
1B	CO10048455	Updating to reflect the correct G1 certificate
1C	CO10051993	Updating to reflect the correct Carmeda G1 certificate
1D	CO10069170	Updated cover page, header, and footer to current format; Updated Quality Certificate and Product Certificate numbers, changed signatory to Sue Fidler (Senior Manager, Regulatory Affairs); Updated ISO 13485 to current standard
1E	CO10118710	Removed OBS model numbers per OPN 1444 and OPN 1695. Added models 87520, 87522, 87524 which is in TF-0051, but inadvertently omitted from the DoC. Replaced 81127 with 81124 to correct typographical error in model number; the correct model has always been 81124. Deleted duplicative model number froms Curved Tip With Flange, Wirewound Arterial Cannulae Family. Updated to new Template (11025 Rev 1D). Removed Curved Tip With Flange, Wirewound Arterial Cannulae, as those model numbers were duplicates of models in the same family. Removed duplicates of CB87920, CB87922.
1F	CO10133712	Update Quality Systems Certificate Number
1G	CO10133376	Removed duplicative model numbers (87920 and 87922), listed twice in Family M. Added models present in TF-0051, but inadvertently omitted from the Declaration (72720, 72724, 72820, 72822, 72824). Omitted models being discontinued as part of the Class III recertification (CB76320, CB76322, CB76324).
1H	CO10163512	Update Declaration of Conformity to reflect new EC Quality System Certificate number Update Declaration of Conformity to reflect new EC Design Examination Certificate number Added Cortiva products Add classification Rule 17 for all Carmeda and Cortiva products Update Manufacturer information Update EC Representative information Update to Notified Body information Removal of obsolete models Correction to declaration statement

1J	CO10179557	Update Declaration of Conformity to reflect new EC Design Examination Certificate numbers Corrected Design Exam Certificate numbers for drug coated arterial cannula to move models CB75318 and CB75320 from "Select Series™ Straight Tip Arterial Cannula" to "DLP™ Straight Tip Arterial Cannula."
1K	CO10218833	Update certificate numbers from G1 16 08 39709 01060 to G1 16 80 3909 01060 Remove Vention as a facility, as it is not on any MDT Quality certs
1L	CO10267237	Update DoC to reflect TF-0051 updates in CO10166821 and CO10267237 Added ISO Quality System Certificate number
1M	RCH00027815	Created on new DoC template, removed Carmeda references, updated Appendix B to correct the standard version to ISO 13485:2016 and applied standards reference.
AA	RCH00060389	Add G1 15 09 39709 992 for Cortiva™ Coated Products. Remove the QS from the certificate header(s) in Attachment A. Update EC Quality System Certificate from G1 16 08 39709 01060 to G1 039709 1263 Rev. 00 Update template Update the manufacturer address
AB	RCH00073666	Updated EC Quality System Certificates G1 15 09 39709 992 with G1 039709 1318 Rev. 00, updated EC Design Examination Certificate(s) G7 16 05 39709 01050 with G7 039709 1297 Rev. 00, and updated EC Certificate G1 039709 Rev. 00 with G1 039709 1304 Rev. 00 Updated Manufacturer address Update format
AC	RCH00106378	Update device descriptions to match labeling

EC Declaration of Conformity

Manufacturer:	Medtronic, Inc. 710 Medtronic Parkway N.E. Minneapolis MN 55432 USA
EC Representative	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen THE NETHERLANDS
Design Facility:	Medtronic Perfusion Systems 7611 Northland Drive Minneapolis, MN 55428 USA
Manufacturing Facility	Medtronic Mexico S.de R.L. de CV Av. Paseo Cucapah 10510 El Lago C.P. 22210 Tijuana, Baja California, MEXICO
Product:	See Attachment A
Classification, Rules:	Class IIa, Rule 7 (Uncoated models) Class III, Rule 7, 13 & 17 (Cortiva™ Coated models)
Conformity Assessment Route	Annex II. 3 (for Class IIa) Annex II. 3 (for Class III)
Standards Applied:	See **Attachment B**
Notified Body:	TÜV SÜD Product Service GmbH Zertifizierstelle Ridlerstraße 65 80339 München GERMANY
Identification Number:	0123
EC Quality System Certificate:	G1 039709 1304 REV. 00 (Uncoated products) G1 039709 1318 REV. 00 (Cortiva™ Coated Products)
EC Design Examination Certificate(s):	G7 039709 1297 REV. 00 (Cortiva™ Coated Products)

We, Medtronic, hereby declare under our sole responsibility that the Medical Device(s) categories specified above and provided with the CE marking, meet the provisions of the EC Council Directive 93/42/EEC of 14 June 1993 as amended by 2007/47/EC which apply to them.

This declaration is supported by the Certificate(s) according to the provisions of relevant Annex(es) of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Place of Issue: Minneapolis, MN USA

Authorized Signature:

Name: Michael Green
Title: Senior Regulatory Affairs Manager
Date: 22 Sept 2020

Attachment A to Declaration of Conformity DC1051

This attachment specifies the uncoated and Cortiva-coated products included in the referenced Declaration of Conformity. The following is an outline of the list of products presented in each section of this attachment:

Uncoated Products

1. EOPA Cannulae
2. EOPA CAP Cannulae
3. EOPA Cannulae – Elongated One Piece
4. Ultraflex Cannulae
5. Select 3D® II Cannulae
6. Straight Tip Arterial Cannulae
7. One Piece Arterial Cannulae
8. Select Series Cannulae
9. Select CAP Cannulae (obsolete)
10. Metal Tip Cannulae
11. Descending Arch Cannulae (obsolete)
12. Flexible Arch Cannulae
13. Curved Tip Cannulae
14. Wirewound Arterial Cannulae

Cortiva™ Coated Products

15. EOPA™ Elongated One-Piece Arterial Cannulae
16. EOPA 3D™ Arterial Cannulae
17. DLP™ One-Piece Pediatric Arterial Cannulae
18. DLP™ Flexible Arch Arterial Cannulae
19. DLP™ Straight Tip Arterial Cannulae
20. DLP® Curved Tip Arterial Cannulae
21. DLP™ Curved Metal Tip Arterial Cannulae
22. Select Series™ Straight Tip Arterial Cannulae
23. Select 3D™ II Arterial Cannulae

1. EOPA Cannulae

Device Description	Model Number	Variant(s)	MDD Rule	Certificate
EOPA 3D® Arterial Cannula 20 Fr	78220	NA	7	G1 039709 1304 REV. 00
EOPA 3D® Arterial Cannula 22 Fr	78222	NA	7	G1 039709 1304 REV. 00
EOPA 3D® Arterial Cannula 20 Fr	78320	NA	7	G1 039709 1304 REV. 00
EOPA 3D® Arterial Cannula 22 Fr	78322	NA	7	G1 039709 1304 REV. 00

2. EOPA CAP Cannulae

Device Description	Model Number	Variant(s)	MDD Rule	Certificate
EOPA CAP™ Elongated One-Piece Arterial Cannula 18 Fr.	77818	NA	7	G1 039709 1304 REV. 00
EOPA CAP™ Elongated One-Piece Arterial Cannula 20 Fr.	77820	NA	7	G1 039709 1304 REV. 00
EOPA CAP™ Elongated One-Piece Arterial Cannula 22 Fr.	77822	NA	7	G1 039709 1304 REV. 00
EOPA CAP™ Elongated One-Piece Arterial Cannula 18 Fr.	77918	NA	7	G1 039709 1304 REV. 00
EOPA CAP™ Elongated One-Piece Arterial Cannula 20 Fr.	77920	NA	7	G1 039709 1304 REV. 00
EOPA CAP™ Elongated One-Piece Arterial Cannula 22 Fr.	77922	NA	7	G1 039709 1304 REV. 00

3. EOPA Cannulae – Elongated One Piece

Device Description	Model Number	Variant(s)	MDD Rule	Certificate
EOPA™ – Elongated One Piece Arterial Cannula 18 Fr.	77418	NA	7	G1 039709 1304 REV. 00
EOPA™ – Elongated One Piece Arterial Cannula 20 Fr.	77420	NA	7	G1 039709 1304 REV. 00
EOPA™ – Elongated One Piece Arterial Cannula 22 Fr.	77422	NA	7	G1 039709 1304 REV. 00
EOPA™ – Elongated One Piece Arterial Cannula 24 Fr.	77424	NA	7	G1 039709 1304 REV. 00
EOPA™ – Elongated One Piece Arterial Cannula 18 Fr.	77518	NA	7	G1 039709 1304 REV. 00
EOPA™ – Elongated One Piece Arterial Cannula 20 Fr.	77520	NA	7	G1 039709 1304 REV. 00
EOPA™ – Elongated One Piece Arterial Cannula 22 Fr.	77522	NA	7	G1 039709 1304 REV. 00
EOPA™ – Elongated One Piece Arterial Cannula 24 Fr.	77524	NA	7	G1 039709 1304 REV. 00
EOPA™ – Elongated One Piece Arterial Cannula 18 Fr.	77618	NA	7	G1 039709 1304 REV. 00
EOPA™ – Elongated One Piece Arterial Cannula 20 Fr.	77620	NA	7	G1 039709 1304 REV. 00
EOPA™ – Elongated One Piece Arterial Cannula 22 Fr.	77622	NA	7	G1 039709 1304 REV. 00
EOPA™ – Elongated One Piece Arterial Cannula 24 Fr.	77624	NA	7	G1 039709 1304 REV. 00
EOPA – Elongated One Piece Arterial Cannula 18 Fr.	77718	NA	7	G1 039709 1304 REV. 00
EOPA™ – Elongated One Piece Arterial Cannula 20 Fr.	77720	NA	7	G1 039709 1304 REV. 00
EOPA™ – Elongated One Piece Arterial Cannula 22 Fr.	77722	NA	7	G1 039709 1304 REV. 00
EOPA™ – Elongated One Piece Arterial Cannula 24 Fr.	77724	NA	7	G1 039709 1304 REV. 00

4. Ultraflex Cannulae

Device Description	Model Number	Variant(s)	MDD Rule	Certificate
DLP® Straight Tip Arterial Cannula 22 Fr.	74322	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 20 Fr.	81020	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 22 Fr.	81022	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 20 Fr.	81120	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 22 Fr.	81122	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 20 Fr.	82020	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 22 Fr.	82022	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 20 Fr.	82120	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 22 Fr.	82122	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 24 Fr.	81024	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 24 Fr.	82024	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 24 Fr.	81124	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 24 Fr.	82124	4NA	7	G1 039709 1304 REV. 00

5. Select 3D® II Cannulae

Device Description	Model Number	Variant(s)	MDD Rule	Certificate
Select 3D® II Arterial Cannula 20 Fr.	78420	NA	7	G1 039709 1304 REV. 00
Select 3D® II Arterial Cannula 22 Fr.	78422	NA	7	G1 039709 1304 REV. 00
Select 3D® II Arterial Cannula 24 Fr.	78424	NA	7	G1 039709 1304 REV. 00
Select 3D® II Arterial Cannula 20 Fr.	78520	NA	7	G1 039709 1304 REV. 00
Select 3D® II Arterial Cannula 22 Fr.	78522	NA	7	G1 039709 1304 REV. 00
Select 3D® II Arterial Cannula 24 Fr.	78524	NA	7	G1 039709 1304 REV. 00

6. Straight Tip Arterial Cannulae

Device Description	Model Number	Variant(s)	MDD Rule	Certificate
DLP® Straight Tip Arterial Cannula 16 Fr.	73016	NA	7	G1 039709 1304 REV. 00
DLP® Straight Tip Arterial Cannula 18 Fr.	76118	NA	7	G1 039709 1304 REV. 00
DLP® Straight Tip Arterial Cannula 20 Fr.	76320	NA	7	G1 039709 1304 REV. 00
DLP® Straight Tip Arterial Cannula 22 Fr.	76322	NA	7	G1 039709 1304 REV. 00
DLP® Straight Tip Arterial Cannula 24	76324	NA	7	G1 039709 1304 REV. 00
DLP® Straight Tip Arterial Cannula 16 Fr.	70016	NA	7	G1 039709 1304 REV. 00
DLP® Straight Tip Arterial Cannula 8 Fr.	75008	NA	7	G1 039709 1304 REV. 00
DLP® Straight Tip Arterial Cannula 10 Fr.	75010	NA	7	G1 039709 1304 REV. 00
DLP® Straight Tip Arterial Cannula 12	75012	NA	7	G1 039709 1304 REV. 00
DLP® Straight Tip Arterial Cannula 14 Fr.	75014	NA	7	G1 039709 1304 REV. 00
DLP® Straight Tip Arterial Cannula 18 Fr.	75318	NA	7	G1 039709 1304 REV. 00
DLP® Straight Tip Arterial Cannula 20 Fr.	75320	NA	7	G1 039709 1304 REV. 00
DLP® Straight Tip Arterial Cannula 22 Fr.	75322	NA	7	G1 039709 1304 REV. 00
DLP® Straight Tip Arterial Cannula 24 Fr.	75324	NA	7	G1 039709 1304 REV. 00
DLP® Straight Tip Arterial Cannula 20 Fr.	76020	NA	7	G1 039709 1304 REV. 00
DLP® Straight Tip Arterial Cannula 22 Fr.	76022	NA	7	G1 039709 1304 REV. 00
DLP® Straight Tip Arterial Cannula 24 Fr.	76024	NA	7	G1 039709 1304 REV. 00
DLP® Straight Tip Arterial Cannula 20 Fr.	76120	NA	7	G1 039709 1304 REV. 00
DLP® Straight Tip Arterial Cannula 22 Fr.	76122	NA	7	G1 039709 1304 REV. 00
DLP® Straight Tip Arterial Cannula 24 Fr.	76124	NA	7	G1 039709 1304 REV. 00

7. One Piece Arterial Cannulae

Device Description	Model Number	Variant(s)	MDD Rule	Certificate
DLP™ One-Piece Arterial Cannulae, Pediatric 6 Fr	77006	NA	7	G1 039709 1304 REV. 00
DLP™ One-Piece Arterial Cannulae, Pediatric 6 Fr	77106	NA	7	G1 039709 1304 REV. 00
DLP™ One-Piece Pediatric Arterial Cannula 6 Fr	77206	NA	7	G1 039709 1304 REV. 00
DLP™ One-Piece Pediatric Arterial Cannula 8 Fr	77208	NA	7	G1 039709 1304 REV. 00
DLP™ One-Piece Pediatric Arterial Cannula 10 Fr	77210	NA	7	G1 039709 1304 REV. 00
DLP™ One-Piece Pediatric Arterial Cannula 12 Fr	77212	NA	7	G1 039709 1304 REV. 00
DLP™ One-Piece Pediatric Arterial Cannula 6 Fr	77306	NA	7	G1 039709 1304 REV. 00
DLP™ One-Piece Pediatric Arterial Cannula 8 Fr	77308	NA	7	G1 039709 1304 REV. 00
DLP™ One-Piece Pediatric Arterial Cannula 10 Fr	77310	NA	7	G1 039709 1304 REV. 00
DLP™ One-Piece Pediatric Arterial Cannula 12 Fr	77312	NA	7	G1 039709 1304 REV. 00
DLP™ One-Piece Pediatric Arterial Cannula 8 Fr	77008	NA	7	G1 039709 1304 REV. 00
DLP™ One-Piece Pediatric Arterial Cannula 10 Fr	77010	NA	7	G1 039709 1304 REV. 00
DLP™ One-Piece Pediatric Arterial Cannula 8 Fr	77012	NA	7	G1 039709 1304 REV. 00
DLP™ One-Piece Pediatric Arterial Cannula 14 Fr	77014	NA	7	G1 039709 1304 REV. 00
DLP™ One-Piece Pediatric Arterial Cannula 16 Fr	77016	NA	7	G1 039709 1304 REV. 00
DLP™ One-Piece Pediatric Arterial Cannula 8 Fr	77108	NA	7	G1 039709 1304 REV. 00
DLP™ One-Piece Pediatric Arterial Cannula 10 Fr	77110	NA	7	G1 039709 1304 REV. 00
DLP™ One-Piece Pediatric Arterial Cannula 12 Fr	77112	NA	7	G1 039709 1304 REV. 00
DLP™ One-Piece Pediatric Arterial Cannula 14 Fr	77114	NA	7	G1 039709 1304 REV. 00
DLP™ One-Piece Pediatric Arterial Cannula 16 Fr	77116	NA	7	G1 039709 1304 REV. 00

8. Select Series™ Cannulae

Device Description	Model Number	Variant(s)	MDD Rule	Certificate
Select Series™ Straight Tip Arterial Cannula 20 Fr.	72120	NA	7	G1 039709 1304 REV. 00
Select Series™ Straight Tip Arterial Cannula 22 Fr.	72122	NA	7	G1 039709 1304 REV. 00
Select Series™ Straight Tip Arterial Cannula 24 Fr.	72124	NA	7	G1 039709 1304 REV. 00
Select Series™ Straight Tip Arterial Cannula 20 Fr.	72220	NA	7	G1 039709 1304 REV. 00
Select Series™ Straight Tip Arterial Cannula 22 Fr.	72222	NA	7	G1 039709 1304 REV. 00
Select Series™ Straight Tip Arterial Cannula 24 Fr.	72224	NA	7	G1 039709 1304 REV. 00
Select Series™ Arterial Cannula 22 Fr.	72622	NA	7	G1 039709 1304 REV. 00
Select Series™ Angled Tip Arterial Cannula 20 Fr.	72420	NA	7	G1 039709 1304 REV. 00
Select Series™ Angled Tip Arterial Cannula 22 Fr.	72422	NA	7	G1 039709 1304 REV. 00
Select Series™ Angled Tip Arterial Cannula 24Fr.	72424	NA	7	G1 039709 1304 REV. 00
Select Series™ Angled Tip Arterial Cannula 20 Fr.	72520	NA	7	G1 039709 1304 REV. 00
Select Series™ Angled Tip Arterial Cannula 22 Fr.	72522	NA	7	G1 039709 1304 REV. 00
Select Series™ Angled Tip Arterial Cannula 24 Fr.	72524	NA	7	G1 039709 1304 REV. 00
Select Series™ Angled Tip Arterial Cannula 20 Fr.	72720	NA	7	G1 039709 1304 REV. 00
Select Series™ Angled Tip Arterial Cannula 22 Fr.	72722	NA	7	G1 039709 1304 REV. 00
Select Series™ Angled Tip Arterial Cannula 24 Fr.	72724	NA	7	G1 039709 1304 REV. 00
Select Series™ Angled Tip Arterial Cannula 20 Fr.	72820	NA	7	G1 039709 1304 REV. 00
Select Series™ Angled Tip Arterial Cannula 22 Fr.	72822	NA	7	G1 039709 1304 REV. 00
Select Series™ Angled Tip Arterial Cannula 24 Fr.	72824	NA	7	G1 039709 1304 REV. 00
Select Series™ Angled Tip Arterial Cannula 20 Fr.	73420	NA	7	G1 039709 1304 REV. 00
Select Series™ Angled Tip Arterial Cannula 22 Fr.	73422	NA	7	G1 039709 1304 REV. 00
Select Series™ Angled Tip Arterial Cannula 24 Fr.	73424	NA	7	G1 039709 1304 REV. 00
Select Series™ Angled Tip Arterial Cannula 20 Fr.	73520	NA	7	G1 039709 1304 REV. 00

Select Series™ Angled Tip Arterial Cannula 22 Fr.	73522	NA	7	G1 039709 1304 REV. 00
Select Series™ Angled Tip Arterial Cannula 24 Fr.	73524	NA	7	G1 039709 1304 REV. 00

9. Select CAP™ Cannulae (obsolete)

10. Metal Tip Cannulae

Device Description	Model Number	Variant(s)	MDD Rule	Certificate
DLP® Curved Metal Tip Arterial Cannula 20 Fr.	80020	NA	7	G1 039709 1304 REV. 00
DLP® Curved Metal Tip Arterial Cannula 22 Fr.	80022	NA	7	G1 039709 1304 REV. 00
DLP® Curved Metal Tip Arterial Cannula 24 Fr.	80024	NA	7	G1 039709 1304 REV. 00
DLP® Curved Metal Tip Arterial Cannula 20 Fr.	80120	NA	7	G1 039709 1304 REV. 00
DLP® Curved Metal Tip Arterial Cannula	80122	NA	7	G1 039709 1304 REV. 00
DLP® Curved Metal Tip Arterial Cannula 24 Fr.	80124	NA	7	G1 039709 1304 REV. 00
DLP® Curved Metal Tip Arterial Cannula 20 Fr.	80220	NA	7	G1 039709 1304 REV. 00
DLP® Curved Metal Tip Arterial Cannula 22 Fr.	80222	NA	7	G1 039709 1304 REV. 00
DLP® Curved Metal Tip Arterial Cannula 24 Fr.	80224	NA	7	G1 039709 1304 REV. 00
DLP® Curved Metal Tip Arterial Cannula 20 Fr.	80320	NA	7	G1 039709 1304 REV. 00
DLP® Curved Metal Tip Arterial Cannula 22 Fr.	80322	NA	7	G1 039709 1304 REV. 00
DLP® Curved Metal Tip Arterial Cannula 24 Fr.	80324	NA	7	G1 039709 1304 REV. 00

11. Descending Arch Cannulae (obsolete)

12. Flexible Arch Cannulae

Device Description	Model Number	Variant(s)	MDD Rule	Certificate
DLP® Flexible Arch Arterial Cannula 20 Fr.	70420	NA	7	G1 039709 1304 REV. 00
DLP® Flexible Arch Arterial Cannula 22 Fr.	70422	NA	7	G1 039709 1304 REV. 00
DLP® Flexible Arch Arterial Cannula 24 Fr.	70424	NA	7	G1 039709 1304 REV. 00
DLP® Flexible Arch Arterial Cannula 20 Fr.	71420	NA	7	G1 039709 1304 REV. 00
DLP® Flexible Arch Arterial Cannula 22 Fr.	71422	NA	7	G1 039709 1304 REV. 00
DLP® Flexible Arch Arterial Cannula 24 Fr.	71424	NA	7	G1 039709 1304 REV. 00

13. Curved Tip Cannulae

Device Description	Model Number	Variant(s)	MDD Rule	Certificate
DLP® Curved Tip Arterial Cannula 20 Fr.	87020	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 22 Fr.	87022	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 20 Fr.	87920	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 22 Fr.	87922	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 20 Fr.	87120	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 22 Fr.	87122	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 24 Fr.	87124	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 20 Fr.	87220	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 22 Fr.	87222	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 24 Fr.	87224	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 24 Fr.	87024	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 24 Fr.	87924	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 20 Fr.	83020	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 22 Fr.	83022	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 24 Fr.	83024	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 20 Fr.	84020	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 22 Fr.	84022	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 24 Fr.	84024	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 20 Fr.	88020	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 22 Fr.	88022	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 24 Fr.	88024	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 20 Fr.	88120	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 22 Fr.	88122	NA	7	G1 039709 1304 REV. 00

DLP® Curved Tip Arterial Cannula 24 Fr.	88124	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 20 Fr.	89020	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 22 Fr.	89022	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 24 Fr.	89024	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 20 Fr.	89120	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 22 Fr.	89122	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 24 Fr.	89124	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 24 Fr.	87520	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 24 Fr.	87522	NA	7	G1 039709 1304 REV. 00
DLP® Curved Tip Arterial Cannula 24 Fr.	87524	NA	7	G1 039709 1304 REV. 00

14. Wirewound Arterial Cannulae

Device Description	Model Number	Variant(s)	MDD Rule	Certificate
Wirewound Arterial Cannula With Clamp Site	72024	NA	7	G1 039709 1304 REV. 00

15. EOPA™ Elongated One-Piece Arterial Cannulae with Cortiva Coating

Device Description	Model Number	Variant(s)	MDD Rule	Certificate
EOPA™ Elongated One-Piece Arterial Cannulae with Cortiva™ BioActive Surface	CB77418 CB77420 CB77422 CB77424 CB77518 CB77520 CB77522 CB77524 CB77618 CB77620 CB77622 CB77624 CB77718 CB77720 CB77722 CB77724	NA	13, 17	G7 039709 1297 REV. 00

16. EOPA 3D™ Arterial Cannulae with Cortiva Coating

Device Description	Model Number	Variant(s)	MDD Rule	Certificate
EOPA 3D™ Arterial Cannulae with Cortiva™ BioActive Surface	CB78222 CB78322	NA	7, 13, 17	G7 039709 1297 REV. 00

17. DLP™ One-Piece Pediatric Arterial Cannulae with Cortiva Coating

Device Description	Model Number	Variant(s)	MDD Rule	Certificate
DLP™ One-Piece Pediatric Arterial Cannulae with Cortiva™ BioActive Surface	CB77006 CB77008 CB77010 CB77012 CB77014 CB77016 CB77106 CB77108 CB77110 CB77112 CB77114 CB77116	NA	7, 13, 17	G7 039709 1297 REV. 00

18. DLP™ Flexible Arch Arterial Cannulae with Cortiva Coating

Device Description	Model Number	Variant(s)	MDD Rule	Certificate
DLP™ Flexible Arch Arterial Cannulae with Cortiva™ BioActive Surface	CB71420 CB71422 CB71424	NA	7, 13, 17	G7 039709 1297 REV. 00

19. DLP™ Straight Tip Arterial Cannulae

Device Description	Model Number	Variant(s)	MDD Rule	Certificate
DLP™ Straight Tip Arterial Cannulae with Cortiva™ BioActive Surface	CB75318 CB75320 CB76120 CB76122 CB76124	NA	7, 13, 17	G7 039709 1297 REV. 00

20. DLP® Curved Tip Arterial Cannulae with Cortiva Coating

Device Description	Model Number	Variant(s)	MDD Rule	Certificate
DLP™ Curved Tip Arterial Cannulae with Cortiva™ BioActive Surface	CB81120 CB81122 CB87022 CB87222 CB89122	NA	7, 13, 17	G7 039709 1297 REV. 00

21. DLP™ Curved Metal Tip Arterial Cannulae with Cortiva Coating

Device Description	Model Number	Variant(s)	MDD Rule	Certificate
DLP™ Curved Metal Tip Arterial Cannulae with Cortiva™ BioActive Surface	CB80120	NA	7, 13, 17	G7 039709 1297 REV. 00

22. Select Series™ Straight Tip Arterial Cannulae with Cortiva Coating

Device Description	Model Number	Variant(s)	MDD Rule	Certificate
Select Series™ Straight Tip Arterial Cannulae with Cortiva™ BioActive Surface	CB72120 CB72122 CB72224 CB72124	NA	7, 13, 17	G7 039709 1297 REV. 00

23. Select 3D™ II Arterial Cannulae with Cortiva Coating

Device Description	Model Number	Variant(s)	MDD Rule	Certificate
Select 3D™ II Arterial Cannulae with Cortiva™ BioActive Surface	CB78422 CB78522	NA	7, 13, 17	G7 039709 1297 REV. 00

Attachment B to the Declaration of Conformity DC1051: Applicable Standards

The below mentioned Standards apply to all the product(s) mentioned on the applicable CE Mark certificate.

Standard Number	Description
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes.

Refer to TF-0051 and WKG-1007 for applied standards.

Rev	CO#	Description of Change
1A	CO10042951	Introduce new EU Declaration of Conformity specific to uncoated and coated Venous Cannulae
1B	CO10048455	Updating to reflect the correct G1 certificate
1C	CO10051993	Updating to reflect the correct Carmeda G1 certificate
1D	CO10065339	Update Declaration of Conformity DC1063 with: New EC Design Examination Certificate Numbers New revision of EN ISO 13485 standard
1E	CO10066336	Uncoated DLP Single Stage Venous Cannula with Right Angle Metal Tip model number 69428 was inadvertently omitted from Section C. Revision 1E serves to add this model to this Declaration of Conformity; thereby correcting this omission.
1F	CO10133712	Update Quality Systems Certificate Number and Header Format
1G	CO10163515	Update Declaration of Conformity to reflect new EC Quality System Certificate number Update Declaration of Conformity to reflect new EC Design Examination Certificate number Added Cortiva products Add classification Rule 17 for all Carmeda and Cortiva products Update Manufacturer information Update EC Representative information Update to Notified Body information Removal of obsolete models Correction to declaration statement
1H	CO10219346	Update certificate numbers from G1 16 08 39709 01060 to G1 16 80 3909 01060 Updated addresses to align with certificates Added classification to attachment A to align with template per SOP31347 Added Rule 7 for all Class III devices Updated logo on letterhead Updated products name and device description to align with the Technical File. Removed Template number from footnote
1J	RCH00027815	Created on new DoC template, removed references to Carmeda, updated standard number to ISO 13485:2016 and applied standards reference.
AA	RCH00060389	Update EC Quality System Certificate from G1 16 08 39709 01060 to G1 039709 1263 Rev. 00 Update Manufacturer address Update template and minor formatting changes
AB	RCH00073666	Updated EC Quality System Certificates G1 15 09 39709 992 with G1 039709 1318 Rev. 00, updated EC Design Examination Certificate(s) G7 15 12 39709 01019 with G7 039709 1316 Rev. 00 and updated G1 039709 1263 Rev. 00 with G1 039709 1304 Rev. 00. Updated Manufacturer and Manufacturing site address Update format

AC	RCH00062289	Removed obsolete CFNs 93451C and 97029 from scope
AD	RCH00106378	Updated the section titles to the following: Section 3: From DLP™ Single Stage Venous Cannulae with Right Angle Metal Tip to DLP™ to Single Stage Venous Cannulae Section 5: From DLP™ Silicone Single Stage Venous Cannulae with Inflatable Cuff to DLP™ Venous Return Cannulae Section 8: From VC2™ Atrial-Caval Venous Cannulae to VC2™ Venous Cannulae Section 9: From VC2™ Atrial-Caval Cannulae to VC2™ Venous Cannulae Section 13: From VC2™ Atrial-Caval Venous Cannulae to VC2™ Venous Cannulae

EC Declaration of Conformity

Manufacturer	Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN 55432 USA
EC Representative	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen THE NETHERLANDS
Design Facility	Medtronic Perfusion Systems 7611 Northland Drive Minneapolis, MN 55428 USA
Manufacturing Facility	Medtronic Mexico S. De R.L. de CV Av. Paseo Cucapah 1051 El Lago C.P 22210. Tijuana, Baja California, MEXICO
Product	**Reference Attachment A**
Classification, Rules	Class IIa, Rule 7 (Uncoated models) Class III, Rule 7, 13 & 17 (Cortiva™ Coated models)
Conformity Assessment Route	Annex II.3 (for Class IIa) Annex II.3 combined with II.4 (for Class III)

I, the undersigned, hereby declare that the Medical Devices specified above and provided with the CE marking, meet the provisions of Council Directive 93/42/EEC of 14 June 1993 as modified by directive 2007/47, which apply to them. This declaration is supported by the Certificates according to the provisions of relevant Annex of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Standards Applied: **Reference Attachment B**

Notified Body:	TÜV SÜD Product Service GmbH Zertifizierstelle Ridlerstraße 65 80339 München GERMANY
Identification Number:	0123
EC Quality System Certificate:	G1 039709 1304 REV. 00 (Uncoated products) G1 039709 1318 REV. 00 (Cortiva™ Coated Products)
EC Design Examination Certificate(s):	G7 039709 1316 REV. 00 (Cortiva™ Coated Products)
Place of Issue:	Minneapolis, Minnesota USA

Authorized Signature:

Name: Michael Green
Title: Senior Regulatory Affairs Manager
Date: 22 Sept 2020

Attachment A to Declaration of Conformity DC1063

This attachment specifies the uncoated, Cortiva coated products included in the above referenced Declaration of Conformity. The following is an outline of the list of products presented in each section of this attachment:

Uncoated Products

1. Multi-Stage Venous Cannulae
2. Malleable Venous Cannulae
3. Single-Stage, Right Angle Metal Tip Venous Cannulae
4. Single Stage Venous Cannulae
5. Single Stage Balloon Tip Venous Cannulae
6. Single Stage Basket Tip Venous Cannulae
7. VAD Cannulae for Ventricular Assist
8. VC2™ Atrial-Caval Venous Cannulae
9. OVAL VC2™ Atrial-Caval Cannulae
10. MC2™ Two-Stage Venous Cannulae
11. OVAL MC2™ Two-Stage Venous Cannulae
12. Thin Wall Two-Stage Venous Cannulae
13. VC2™ Atrial-Caval Venous Cannulae
14. ULTRAFLEX Venous Cannulae

Cortiva™ Coated Products

15. MC2X™ Three Stage Venous Cannulae
16. DLP™ Malleable Single Stage Venous Cannulae
17. DLP™ Single Stage Right Angle Metal Tip Venous Cannulae
18. DLP™ Single Stage Venous Cannulae
19. DLP™ Single Stage Right Angle Venous Cannulae
20. VC2™ Atrial-Caval Venous Cannulae
21. MC2™ Two Stage Venous Cannulae
22. MC2X™ Three Stage Venous Cannulae

1. MC2X™ Three Stage Venous Cannulae

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
MC2X® Multi-Stage Venous Cannulae	91429 91429C 91437 91437C	IIa	NA	7	G1 039709 1304 REV. 00

2. DLP™ Malleable Single Stage Venous Cannulae

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
DLP® Malleable Venous Cannulae	68112 68114 68116 68118 68120 68122 68124 68126 68128 68130 68132 68134 68136 68138 68140	IIa	NA	7	G1 039709 1304 REV. 00

3. DLP™ Single Stage Venous Cannulae

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
DLP™ Single Stage Venous Cannulae	67312 67314 67316 67318 67320 69312 69314 69316 69318 69320 69322 69324 69328 69331 69424 69428 69431	IIa	NA	7	G1 039709 1304 REV. 00
DLP™ Single Stage Venous Cannulae, Pack of 10	67300 69300	IIa	NA	7	G1 039709 1304 REV. 00

4. DLP™ Single Stage Venous Cannulae

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
DLP™ Single Stage Venous Cannulae	66112 66114 66116 66118 66120 66122 66124 66126 66128 66130 66132 66134 66136 66140 66236 66238 66240 67512 67514 67516 67518 67520 67522 67524 67528 67530 67532 67534 67536 67540 67636 67640 67526 67638 69528 69531	IIa	NA	7	G1 039709 1304 REV. 00

5. DLP™ Venous Return Cannulae

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
DLP™ Venous Return Cannulae	91037	IIa	NA	7	G1 039709 1304 REV. 00

6. DLP™ Single Stage Venous Cannula with Basket Tip

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
DLP™ Single Stage Basket Tip Venous Cannula	91151	IIa	NA	7	G1 039709 1304 REV. 00

7. DLP™ VAD Cannula for Ventricular Assist

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
DLP® VAD Cannula for Ventricular Assist	95036	IIa	NA	7	G1 039709 1304 REV. 00

8. VC2™ Venous Cannulae

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
VC2™ Venous Cannula	93438 93438C 93448 93448C 93451	IIa	NA	7	G1 039709 1304 REV. 00

9. VC2™ Venous Cannulae

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
VC2™ Venous Cannulae	93463 93463C 93464 93464C	IIa	NA	7	G1 039709 1304 REV. 00

10. MC2™ Two-Stage Venous Cannulae

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
MC2™ Two-Stage Venous Cannulae	91228 91228C 91229 91229C 91236 91236C 91240 91240C 91246 91246C 91251 91251C	IIa	NA	7	G1 039709 1304 REV. 00

11. MC2™ Two-Stage Venous Cannulae

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
OVAL MC2™ Two-Stage Venous Cannulae	91263 91263C 91264 91264C 91265 91265C	IIa	NA	7	G1 039709 1304 REV. 00

12. MC2™ Two-Stage Venous Cannulae

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
MC2 Thin Wall Two-Stage Venous Cannula	91329 91329C	IIa	NA	7	G1 039709 1304 REV. 00

13. VC2™ Venous Cannulae

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
VC2™ Venous Cannula	93548C	IIa	NA	7	G1 039709 1304 REV. 00

14. ULTRAFLEX Venous Cannulae

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
ULTRAFLEX Venous Cannulae	97023	IIa	NA	7	G1 039709 1304 REV. 00

15. MC2X™ Three Stage Venous Cannulae with Cortiva™ BioActive Surface

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
MC2X ™Three Stage Venous Cannulae with Cortiva™ BioActive Surface	CB91429 CB91429C CB91437C	III	NA	7, 13, 17	G7 039709 1316 REV. 00

16. DLP™ Malleable Single Stage Venous Cannulae with Cortiva™ BioActive Surface

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
DLP™ Malleable Single Stage Venous Cannulae with Cortiva™ BioActive Surface	CB68112 CB68114 CB68116 CB68118 CB68120 CB68122 CB68124 CB68126 CB68128 CB68130 CB68132 CB68134 CB68136 CB68138 CB68140	III	NA	7, 13, 17	G7 039709 1316 REV. 00

17. DLP™ Single Stage Right Angle Metal Tip Venous Cannulae with Cortiva™ BioActive Surface

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
DLP™ Single Stage Right Angle Metal Tip Venous Cannulae with Cortiva™BioActive Surface	CB67312 CB67314 CB67316 CB67318 CB67320 CB69320 CB69322 CB69324 CB69328 CB69331 CB69428	III	NA	7, 13, 17	G7 039709 1316 REV. 00

18. DLP™ Single Stage Venous Cannulae with Cortiva™ BioActive Surface

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
DLP™ Single Stage Right Angle Metal Tip Venous Cannulae with Cortiva™ BioActive Surface	CB66112 CB66114 CB66116 CB66118 CB66120 CB66122 CB66124 CB66128 CB66130 CB66132 CB66134 CB66136 CB66236 CB66240	III	NA	7, 13, 17	G7 039709 1316 REV. 00

19. DLP™ Single Stage Right Angle Venous Cannulae

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
DLP™ Single Stage Right Angle Venous Cannulae with Cortiva™ BioActive Surface	CB67512 CB67514 CB67516 CB67518 CB67520 CB67522 CB67524 CB67528 CB67530 CB67532 CB67534 CB67536 CB67636 CB67640	III	NA	7, 13, 17	G7 039709 1316 REV. 00

20. VC2™ Atrial-Caval Venous Cannulae with Cortiva™ BioActive Surface

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
VC2™ Atrial-Caval Venous Cannulae with Cortiva™ BioActive Surface	CB93438C	III	NA	7, 13, 17	G7 039709 1316 REV. 00

21. MC2™ Two Stage Venous Cannulae with Cortiva™ BioActive Surface

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
MC2™ Two Stage Venous Cannulae with Cortiva™ BioActive Surface	CB91228 CB91228C CB91236C CB91240 CB91240C CB91246 CB91246C CB91251C CB91263 CB91263C CB91265 CB91265C CB91329 CB91329C	III	NA	7, 13, 17	G7 039709 1316 REV. 00

22. MC2X™ Three Stage Venous Cannulae with Cortiva™ BioActive Surface

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
MC2™ Three Stage Venous Cannulae with Cortiva™ BioActive Surface	CB91429 CB91429C CB91437C	III	NA	7, 13, 17	G7 039709 1316 REV. 00

Attachment B to the Declaration of Conformity DC1063: Applicable Standards

The below mentioned Standards apply to all the product(s) mentioned on the applicable CE Mark certificate.

Standard Number	Description
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes.

Refer to TF-0063 for a list of applied standards.

Medtronic CORONARY AND STRUCTURAL HEART	Number DC1089	Revision AB	Page 1 of 10
Title: Declaration of Conformity: Cardioplegia Adapters			

Rev	CO#	Description of Change
1A	CO10032125	Introduce new EU Declaration of Conformity specific to Cardioplegia Adapters
1B	CO10049213	Update EC Quality System Certificate number
1C	CO10065225	Update EC Quality System Certificate number, header format, include model 9810064 and EN ISO 13485: 2012/AC:2012
1D	CO10133899	Update Quality Systems Certificate Number and Header Format. Add rule 17 in addition to rule 13.
1E	CO10163517	Update G1 and G7 Carmeda and Cortiva certificates Update Medtronic Address to add "N.E." Add Change classification to Rule 13,17 for all Carmeda/Cortiva products Update to Notified Body address. Update font to Effra. Removed obsoleted models. Added design site and manufacturing sites.
1F	CO10216726	Updated CFN 10003, 10005, and 10007 to match labels Updated uncoated EC Quality System Certificate Number
1G	CO10219507	Removed Vention as a manufacturer Updated Mexico address Updated statement below Conformity Assessment Route to add reference to amendment 2007/47/EC Updated to new logo on letterhead Updated conformity assessment route as per the certificates Added column "Class" to attachment A Added Rule 7 to classification for class III devices (CB10005 and CB14017).
AA	RCH00060389	Update EC Quality System Certificate from G1 16 08 39709 01060 to G1 039709 1263 Rev. 00 Update Manufacturer address Update ISO 13485 standard from 2012 to 2016 Update the template and minor formatting changes
AB	RCH00079603	Updated EC Quality System Certificate from G1 039709 1263 Rev. 00 to G1 039709 1304 Rev. 00 Clarifications to numerous device descriptions to better match product labeling.

EC DECLARATION OF CONFORMITY

Manufacturer:	Medtronic Inc. 710 Medtronic Parkway Minneapolis MN 55432 USA
EC Representative	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen THE NETHERLANDS
Design Facility:	Medtronic Perfusion Systems 7611 Northland Drive Minneapolis, MN 55428 USA
Manufacturing Facility	Medtronic Mexico S.de R.L. de CV Av. Paseo Cucapah 10510 El Lago, C.P. 22210 Tijuana, Baja California, MEXICO
Product:	Attachment A
Classification, Rules:	Class IIa, Rule 2,7 (uncoated) Class III, Rule 7, 13, 17 (Carmeda®/Cortiva™ Coated)
Conformity Assessment Route	Annex II, excluding section (4) (for Class IIa) Annex II, including section (4) (for Class III)

I, the undersigned, hereby declare that the Medical Devices specified above and provided with the CE marking, meet the provisions of Council Directive 93/42/EEC of 14 June 1993 as amended by 2007/47/EC which apply to them. This declaration is supported by the Certificates according to the provisions of relevant Annex of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Title: Declaration of Conformity: Cardioplegia Adapters

Standards Applied:	See Attachment B
Notified Body:	TÜV SÜD Product Service GmbH Zertifizierstelle Ridlerstraße 65 80339 München GERMANY
Identification Number:	0123
EC Quality System Certificate:	G1 039709 1304 Rev. 00 (Uncoated) G1 15 09 39709 992 (Carmeda®/Cortiva™Coated)
EC Design Examination Certificate:	G7 15 12 39709 01030 (Carmeda® Coated) G7 15 12 39709 01031 (Cortiva™ Coated)
Place of Issue:	Minneapolis, Minnesota USA
Authorized Signature:	

Name: Michael Green
Title: Senior Regulatory Affairs Manager
Date: 22/MAY 2020

Attachment A to Declaration of Conformity DC1089

This attachment specifies the uncoated and coated products included in the above referenced Declaration of Conformity. The following is an outline of the list of products presented in each section of this attachment:

A.) Coronary Perfusion Adapters Y-type
B.) Cardioplegia Adapters
C.) Cardioplegia Adapters - Straight
D.) Cardioplegia Adapters - Recirculation
E.) Perfusion Connectors
F.) Perfusion Adapter Sets
G.) Rapid Prime Sets
H.) Adapters
I.) Soft Extension Line
J.) Pressure Monitoring Extension Line
K.) ARISS Selector Switches
L.) Antegrade/Retrograde Adapater
M.) Cardioplegia/Venting
N.) Recirculating/Venting
O.) Cardioplegia Management Set
P.) Multiple Perfusion Sets
Q.) "Y" Type Adapter with Carmeda®/Cortiva™ coating
R.) Multiple Perfusion Set with Carmeda®/Cortiva™ coating

A.) Coronary Perfusion Adapters Y-type

Uncoated

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
DLP® "Y" Adapter – Coronary Perfusion	10004	IIa	10004C 10004D 10004P 10004S 10004UAB	7	G1 039709 1304 Rev. 00

B.) Cardioplegia Adapters

Uncoated

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
DLP® "Y" Adapter	10005	IIa	10005A 10005BH 10005 OS 10005S	7	G1 039709 1304 Rev. 00

C.) Cardioplegia Adapters – Straight

Uncoated

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
DLP® 12.7 cm (5 in) Straight Adapter	10001	IIa	NA	7	G1 039709 1304 Rev. 00
DLP® 12.7 cm (5 in) Straight Adapter	10001C	IIa	NA	7	G1 039709 1304 Rev. 00
DLP® 12.7 cm (5 in) Straight Adapter	10001K	IIa	NA	7	G1 039709 1304 Rev. 00

D.) Cardioplegia Adapters – Recirculation

Uncoated

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
DLP® "Y" Adapter - Recirculating	10003	IIa	NA	7	G1 039709 1304 Rev. 00
DLP® "Y" Adapter - Recirculating	10003OS	IIa	NA	7	G1 039709 1304 Rev. 00
DLP® "Y" Adapter - Recirculating	10003S	IIa	NA	7	G1 039709 1304 Rev. 00

E.) Perfusion Connectors

Uncoated

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
DLP® 0.64 cm (1/4 in) Perfusion Adapter	10007	IIa	10008	7	G1 039709 1304 Rev. 00

F.) Perfusion Adapter Sets

Uncoated

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
DLP® 0.95 cm (3/8 in) x 61.0 cm (24 in) Perfusion Adapter	10020	IIa	NA	7	G1 039709 1304 Rev. 00
DLP® 0.64 cm (1/4 in) x 8.3 cm (3.25 in) Perfusion Adapter	10022	IIa	NA	7	G1 039709 1304 Rev. 00

G.) Rapid Prime Sets

Uncoated

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
DLP® 35.6 cm (14 in) Rapid Prime Set	10021	IIa	NA	7	G1 039709 1304 Rev. 00
DLP® 40.6 cm (16 in) Rapid Prime Set	10023	IIa	NA	7	G1 039709 1304 Rev. 00
DLP® 1.1m (42 in)	10024	IIa	NA	7	G1 039709 1304 Rev. 00

H.) Adapters

Uncoated

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
DLP® "Y" Adapter – Coronary Perfusion	10533	IIa	10534 10535	2	G1 039709 1304 Rev. 00
DLP® 30.5 cm (12 in) Multiple Perfusion Set	14013	IIa	14014 14015 14016 14017 14031	7	G1 039709 1304 Rev. 00
DLP® "Y" Adapter – Coronary Perfusion	10700	IIa	10704 10706 10710	2	G1 039709 1304 Rev. 00

I.) Soft Extension Line

Uncoated

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
DLP® 25.4 cm (10 in) Extension Line Adapter	11001	IIa	11001G	2	G1 039709 1304 Rev. 00

J.) Pressure Monitoring Extension Line

Uncoated

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
DLP® 1.8 m (6 ft) Pressure Monitoring Extension Line Adapter	25009	IIa	25010	7	G1 039709 1304 Rev. 00
DLP® Cardioplegia Adapter with Pressure Port	15004	IIa	NA	7	G1 039709 1304 Rev. 00

K.) ARISS Selectors Switches

Uncoated

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
ARISS® 33.0 cm (13 in) Perfusion Switch	13000	IIa	9810064	7	G1 039709 1304 Rev. 00
ARISS® 33.0 cm (13 in) Perfusion Switch	13004	IIa	NA	7	G1 039709 1304 Rev. 00

L.) Antegrade/Retrograde Adapaters

Uncoated

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
DLP® Antegrade/Retrograde Stopcock Adapter	13001	IIa	NA	7	G1 039709 1304 Rev. 00

M.) Cardioplegia/Venting

Uncoated

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
DLP® Perfusion/Venting Adapter	13002	IIa	NA	7	G1 039709 1304 Rev. 00

N.) Recirculating/Venting

Uncoated

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
DLP® Recirculating/Venting Adapter	13025	IIa	NA	7	G1 039709 1304 Rev. 00

O.) Cardioplegia Management Set

Uncoated

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
DLP® Cardioplegia Management Set	13003	IIa	NA	7	G1 039709 1304 Rev. 00

P.) Multiple Perfusion Sets

Uncoated

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
DLP® 38.1 cm (15 in) Multiple Perfusion Set	14000	IIa	14001 14002 14003 14006 14007 14008	7	G1 039709 1304 Rev. 00

Q) "Y" Type Adapter

Carmeda®/Cortiva™ Coated

Device Description	Model Number	Class	Variant(s)	MDD Rule	Design Exam Certificate
DLP® "Y" Adapter	CB10005	III	NA	7, 13, 17	G7 15 12 39709 01030 (Carmeda®) G7 15 12 39709 01031 (Cortiva™)

R) Multiple Perfusion Sets

Carmeda®/Cortiva™ Coated

Device Description	Model Number	Class	Variant(s)	MDD Rule	Design Exam Certificate
DLP® Multiple Perfusion Sets	CB14017	III	NA	7, 13, 17	G7 15 12 39709 01030 (Carmeda®) G7 1512 39709 01031 (Cortiva™)

Attachment B to the Declaration of Conformity DC1089: Applicable Standards

The below mentioned Standards apply to all the product(s) mentioned on the applicable CE Mark certificate.

Standard Number	Description
EN ISO 13485: 2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes.

For product specific standards refer to the Essential Requirements Checklist for the product in TF-0089 and WKG-1015.

Revision	CO#	Description of Change
1A	CO10041538	Introduce new EU Declaration of Conformity specific to Vents and Sumps
1B	CO10049211	Update EC Quality System Certificate number
1C	CO10065225	Update EC Quality System Certificate number, header format, and EN ISO 13485: 2012/AC:2012
1D	CO10133316	Update Quality System Certificate number and header format
1E	CO10163421	Update Declaration of Conformity to reflect new EC Quality System Certificate number Update Declaration of Conformity to reflect new EC Deisgn Examination Certificate number Add classification Rule 17 for all Carmeda and Cortiva products Update Manufacturer information Update EC Representative information Update to Notified Body information Removal of models: CB12010, CB12013, CB12001, CB12110, CB12113, CB12006 Correction to declaration statement
1F	CO10219507	Update certificate numbers from G1 14 11 39709 952 to G1 16 08 39709 01060 Updated addresses to align with certificates Added classification to attachment A to align with template per SOP31347 Updated statement below "Conformity Assessment Route" section to align with template per SOP31347 Updated logo on letterhead Added Rule #7 to classification rules for Class III devices
AA	RCH00020804	Reformatted table of model numbers to align with Technical File. Updated tables 5 and 6 to remove duplicated models 12113 and 12115 Removed obsoleted model 12524 (Table 9), per PCN 1444. Last lot number 2011101759, expiration date 29-Oct-2011 Added Viant Medical, Inc. as a manufacturing facility Updated quality standard to EN ISO 13485: 2016
AB	RCH00060389	Update EC Quality System Certificate from G1 16 08 39709 01060 to G1 039709 1263 Rev. 00 Update manufacturer address Update template and minor formatting changes Remove Viant as Contract Manufacturer

AC	RCH00073666	Updated EC Quality System Certificates G1 15 09 39709 992 with G1 039709 1318 Rev. 00, update G1 039709 1263 Rev. 00 with G1 039709 1304 Rev. 00 and updated EC Design Examination Certificate(s) G7 15 11 39709 01011 with G7 039709 1299 Rev. 00 Updated Manufacturer address Updated the format
AD	RCH00102964	Update device descriptions to match labeling
AE	RCH00196925	Updating to document template in 31347. European added to row 2 of the DoC, 93/42 EEC information statement added to row 9 of the DoC, added 'Products' to title in attachment A, and updated statement to 'Refer to WKG-1014 and TF-0088, Appendix 1: Applied Standards and Essential Requirements Checklist for the list of applied standards' in Attachment B.

EC Declaration of Conformity

Manufacturer:	Medtronic, Inc. 710 Medtronic Parkway Minneapolis MN 55432USA
European Representative:	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen THE NETHERLANDS
Design Facility:	Medtronic Perfusion Systems 7611 Northland Drive, Minneapolis, MN 55428, USA
Manufacturing Facility:	For Cortiva Coated: Medtronic Mexico S.de R.L. de CV Av. Paseo Cucapah, 10510 El Lago, C.P.22210 Tijuana, Baja California, MEXICO
Product:	Reference **Attachment A**
Classification, Rules:	Class IIa, Rule 7 (Uncoated models) Class III, Rule 7, 13 & 17 (Cortiva™ Coated models)
Conformity Assessment Route	Annex II, excluding section (4) (for Class IIa) Annex II, including section (4) (for Class III)

I, the undersigned, hereby declare that the Medical Devices specified above and provided with the CE marking, meet the provisions of Council Directive 93/42/EEC of 14 June 1993 as amended by 2007/47/EC which apply to them. This declaration is supported by the Certificates according to the provisions of relevant Annex of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Standards Applied:	See **Attachment B**
Notified Body:	TÜV SÜD Product Service GmbH Zertifizierstelle Ridlerstraße 65 80339 München

Identification Number:	GERMANY 0123
EC Quality System Certificate:	G1 039709 1318 REV. 00 (Carmeda® and Cortiva™ Coated Products) G1 039709 1304 Rev. 00 (Uncoated products)
EC Design Examination Certificate:	G7 039709 1299 REV. 00 (Cortiva™ Coated Products)
Place of Issue:	Minneapolis, Minnesota USA

Authorized Signature:

Name: Michael Green
Title: Senior Manager, Regulatory Affairs
Date: 29 Sept 2021

Attachment A to Declaration of Conformity DC1088 Products

This attachment specifies the uncoated and coated products included in the above referenced Declaration of Conformity. The following is an outline of the list of products presented in each section of this attachment:

Uncoated Products

1. DLP® Pericardial Sump
2. DLP® Intracardiac Sump
3. DLP® Pericardial/Intracardiac Sump
4. DLP® Left Heart Vent Catheters
5. DLP® Pulmonary Artery Vent Cannula
6. Aortic Air Aspirating Needle

Cortiva™ Coated Products

7. DLP™ Left Heart Vent Catheter

1. DLP® Pericardial Sump

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
DLP® Pericardial Sump – 38.1 cm (15 in)	12010	IIa	NA	7	G1 039709 1304 Rev. 00

2. DLP® Intracardiac Sump

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
DLP® Intracardiac Sump 20 Fr	12012	IIa	12013	7	G1 039709 1304 Rev. 00

3. DLP® Intracardiac Sump

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
DLP® Pericardial/Intracardiac Sump 20 Fr	12112	IIa	NA	7	G1 039709 1304 Rev. 00

4. DLP® Left Heart Vent Catheters

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
DLP® Left Heart Vent Catheter 13 Fr.	12001	IIa	NA	7	G1 039709 1304 Rev. 00
DLP® Left Heart Vent Catheter 20 Fr.	12002	IIa	NA	7	G1 039709 1304 Rev. 00
DLP® Left Heart Vent Catheter 10 Fr.	12008	IIa	NA	7	G1 039709 1304 Rev. 00
DLP® Left Heart Vent Catheter 16 Fr.	12016	IIa	12101	7	G1 039709 1304 Rev. 00
DLP® Left Heart Vent Catheter 10 Fr.	12110	IIa	12113 12115	7	G1 039709 1304 Rev. 00
DLP® Left Heart Vent Catheter 16 Fr.	12116	IIa	12118	7	G1 039709 1304 Rev. 00
DLP® Left Heart Vent Catheter 20 Fr.	12220	IIa	NA	7	G1 039709 1304 Rev. 00

5. DLP® Pulmonary Artery Vent Cannula

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
DLP® Pulmonary Artery Vent Cannula 16 Fr	12004	IIa	NA	7	G1 039709 1304 Rev. 00

6. DLP® Aortic Air Aspirating Needle

Device Description	Model Number	Class	Variant(s)	MDD Rule	QS Certificate
DLP® Aortic Air Aspirating Needle, 16 Gauge	12006	IIa	NA	7	G1 039709 1304 Rev. 00

7. DLP™ Left Heart Vent Catheter with Cortiva™ BioActive Surface

Device Description	Model Number	Class	Variant(s)	MDD Rule	Design Exam Certificate
DLP™ Left Heart Vent Catheter with Cortiva™ BioActive Surface on the Cannula only	CB12008	IIa III	NA	7, 13, 17	G7 039709 1299 REV. 00

Attachment B to the Declaration of Conformity DC1088: Applicable Standards

The below mentioned Standards apply to all the product(s) mentioned on the applicable CE Mark certificate.

Standard / Directive	Description
EN ISO 13485: 2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes.

Refer to WKG-1014 and TF-0088, Appendix 1: Applied Standards and Essential Requirements Checklist for the list of applied standards.

Rev	CO#	Description of Change
1A	CO10032119	Introduce new EU Declaration of Conformity specific to uncoated and coated Aortic Root Cannulae and Cardioplegia Needles
1B	CO10041528	The section under B for Carmeda Coated should be CB11014 and not CB10114
1C	CO10049196	Update EC Quality System Certificate number
1D	CO10054547	Update EC Quality System Certificate number
1E	CO10065225	Update EC Quality System Certificate number, header format, and EN ISO 13485: 2012/AC:2012
1F	CO10133316	Update EC Quality System Certificate number and header format
1G	CO10162987	Update Declaration of Conformity to reflect new EC Quality System Certificate number Update Declaration of Conformity to reflect new EC Deisgn Examination Certificate number Add classification Rule 17 for all Carmeda and Cortiva products Update Manufacturer information Update EC Representative information Update to Declaration of Conformity Title Update to Notified Body information Removal of models: CB20014, CB10014, CB10016, CB20016, CB10018, CB10012, CB20012, CB11014, CB11012, CB20114, CB10112, CB20112, CB10114, CB10218, CB12218, CB30401, CB30102,

1H	CO10219507	Updated certificate numbers from G1 14 11 39709 952 to G1 16 08 39709 01060 throughout document Updated Notified body address to align with address format on certificates Updated Conformity Assessment Route statement Added Design and the Mexico Manufacturing facilities Added column "Class" to attachment A, to align with template per SOP31347 Updated company logo on header Added Rule #7 for coated devices to Classification rules
1J	RCH00027815	Created on new DoC template, reworded the declaration paragraph on page 2, updated EC Cert number, updated standard number to ISO 13485:2016 and removed Carmeda references and removed obsoleted models.
AA	RCH00060389	Correcting from QS Cert to EC Design Cert in Attachment A Section 9 and 10 for Class III devices. Add G1 15 09 39709 992 for Cortiva™ Coated Products. Remove the QS from the certificate header(s) in Attachment A. Update EC Quality System Certificate from G1 039709 1263 REV. 00 to G1 039709 1263 Rev. 00 Update manufacturer address Update the template and Minor formatting update Removed Viant as contract manufacturer

AB	RCH00073666	Updated EC Quality System Certificates G1 15 09 39709 992 with G1 039709 1318 Rev. 00, updated EC Design Examination Certificate(s) G7 15 11 39709 999 with G7 039709 0999 Rev.01 Updated Manufacturer and updated G1 039709 1263 Rev. 00 with G1 039709 1304 Rev. 00. Updated the format
AC	RCH00106378	Updated product descriptions to match their corresponding labels.

EC DECLARATION OF CONFORMITY

Manufacturer:	Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN 55432 USA
EC Representative	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen THE NETHERLANDS
Design Facility:	Medtronic Perfusion Systems 7611 Northland Drive Minneapolis, MN 55428 USA
Manufacturing Facility	Coating Location (coated models): Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapah 10510 El Lago, C.P.22210 Tijuana, Baja California, MEXICO
Product:	**Attachment A**
Classification, Rules:	Class IIa, Rule 7 (Uncoated models) Class III, Rule 7, 13 & 17 (Cortiva™ Coated models)
Conformity Assessment Route	Annex II, excluding section (4) (for Class IIa) Annex II, including section (4) (for Class III)

I, the undersigned, hereby declare that the Medical Devices specified above and provided with the CE marking, meet the provisions of Council Directive 93/42/EEC of 14 June 1993 as amended by 2007/47/EC which apply to them. This declaration is supported by the Certificates according to the provisions of relevant Annex of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Standards Applied: See **Attachment B**

Notified Body:	TÜV SÜD Product Service GmbH Zertifizierstelle Ridlerstraße 65 80339 München GERMANY
Identification Number:	0123
Quality System Certificate:	Q5 039709 1211
EC Full Quality Assurance Certificate:	G1 039709 1304 REV. 00 (Uncoated Products) G1 039709 1318 REV. 00 (Cortiva™ Coated Products)
EC Design Examination Certificate:	G7 039709 0999 REV. 01 (Cortiva™ Coated Products)
Place of Issue:	Minneapolis, Minnesota USA
Authorized Signature:	

Name: Michael Green
Title: Senior Manager, Regulatory Affairs
Date: 23 Sept 2020

Attachment A to Declaration of Conformity DC1066

This attachment specifies the uncoated and coated products included in the above referenced Declaration of Conformity. The following is an outline of the list of products presented in each section of this attachment:

Uncoated Products

1. Standard Aortic Root Cannulae
2. Standard Aortic Root Cannulae with Flowguard Introducer
3. Long Tip Aortic Root Cannulae
4. Pressure Monitoring Aortic Root Cannulae
5. Pediatric Aortic Root Cannulae
6. Double Lumen Aortic Root Cannulae with Vent Line
7. Minimally Invasive Aortic Root Cannulae (MiAR)
8. Cardioplegia Needles

Cortiva™ Coated Products

9. DLP™ Aortic Root Cannulae
10. DLP™ Aortic Root Cannulae with Vent Line

1. Standard Aortic Root Cannulae

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
DLP® 9 Ga (11 Fr) Aortic Root Cannula	10009	IIa	NA	7	G1 039709 1304 REV. 00
DLP® 12 Ga (9 Fr) Aortic Root Cannula	10012	IIa	NA	7	G1 039709 1304 REV. 00
DLP® 14 Ga (7 Fr) Aortic Root Cannula	10014	IIa	NA	7	G1 039709 1304 REV. 00
DLP® 16 Ga (5 Fr) Aortic Root Cannula	10016	IIa	NA	7	G1 039709 1304 REV. 00
DLP® 18 Ga (4 Fr) Aortic Root Cannula	10018	IIa	NA	7	G1 039709 1304 REV. 00
DLP® 9 Ga (11 Fr) Aortic Root Cannula	20009	IIa	NA	7	G1 039709 1304 REV. 00
DLP® 12 Ga (9 Fr) Aortic Root Cannula	20012	IIa	20012S	7	G1 039709 1304 REV. 00
DLP® 14 Ga (7 Fr) Aortic Root Cannula	20014	IIa	20014L	7	G1 039709 1304 REV. 00
DLP® 16 Ga (5 Fr) Aortic Root Cannula	20016	IIa	NA	7	G1 039709 1304 REV. 00

2. Standard Aortic Root Cannulae with Flow-guard Introducer

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
DLP® 12 Ga (9 Fr) Aortic Root Cannula with Flow-Guard™	11012	IIa	11012L	7	G1 039709 1304 REV. 00
DLP® 14 Ga (7 Fr) Aortic Root Cannula with Flow-Guard™	11014	IIa	11014L	7	G1 039709 1304 REV. 00
DLP® 12 Ga (9 Fr) Aortic Root Cannula with Flow-Guard™ Introducer	21012	IIa	NA	7	G1 039709 1304 REV. 00
DLP® 14 Ga (7 Fr) Aortic Root Cannula with Flow-Guard™ Introducer	21014	IIa	NA	7	G1 039709 1304 REV. 00

3. Long Tip Aortic Root Cannulae

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
DLP® 12 Ga (9 Fr) Aortic Root Cannula	10112	IIa	10112WF	7	G1 039709 1304 REV. 00
DLP® 14 Ga (7 Fr) Aortic Root Cannula	10114	IIa	N/A	7	G1 039709 1304 REV. 00
DLP® 12 Ga (9 Fr) Aortic Root Cannula	20112	IIa	N/A	7	G1 039709 1304 REV. 00
DLP® 14 Ga (7 Fr) Aortic Root Cannula	20114	IIa	20114B 20114HWF 20114WF	7	G1 039709 1304 REV. 00

4. Pressure Monitoring Aortic Root Cannulae

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
DLP® 9 Ga (11 Fr) Aortic Root Cannula	23009	IIa	NA	7	G1 039709 1304 REV. 00
DLP® 9 Ga (11 Fr) Aortic Root Cannula	24009	IIa	NA	7	G1 039709 1304 REV. 00

5. Pediatric Aortic Root Cannulae

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
DLP® 18 Ga (4 Fr) Pediatric Aortic Root Cannula	10218	IIa	NA	7	G1 039709 1304 REV. 00
DLP® 18 Ga (4 Fr) Pediatric Aortic Root Cannula	12218	IIa	NA	7	G1 039709 1304 REV. 00

6. Dual Lumen Aortic Root Cannulae with Vent Line

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
DLP® 12 Ga (9 Fr) Dual Lumen Cardioplegia Cannula	30401	IIa	NA	7	G1 039709 1304 REV. 00
DLP® 12 Ga (9 Fr) Dual Lumen Cardioplegia Cannula	30402	IIa	NA	7	G1 039709 1304 REV. 00

7. Minimally Invasive Aortic Root Cannulae (MiAR)

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
MiAR™ 12 Ga (9 Fr) Aortic Root Cannula with Flow-Guard™	11012L	IIa	11012	7	G1 039709 1304 REV. 00
MiAR™ 14 Ga (7 Fr) Aortic Root Cannula with Flow-Guard™	11014L	IIa	11014	7	G1 039709 1304 REV. 00

8. Cardioplegia Needles

Device Description	Model Number	Class	Variant(s)	MDD Rule	Certificate
DLP® 13 Ga (8 Fr) Cardioplegia Needle – Adult – 1.59 cm (5/8 in) Tip Length	10313	IIa	NA	7	G1 039709 1304 REV. 00
DLP® 16 Ga (5 Fr) Cardioplegia Needle – Neonatal – 0.64 cm (1/4 in) Tip Length	11316	IIa	NA	7	G1 039709 1304 REV. 00

9. DLP™ Aortic Root Cannulae with Cortiva™ BioActive Surface

Device Description	Model Number	Class	Variant(s)	MDD Rule	EC Design Certificate
DLP™ Aortic Root Cannulae with Cortiva™ BioActive Surface	CB10012	III	NA	7, 13, 17	G7 039709 0999 REV.01

10. DLP™ Aortic Root Cannulae with Vent Line with Cortiva™ BioActive Surface

Device Description	Model Number	Class	Variant(s)	MDD Rule	EC Design Certificate
DLP™ Aortic Root Cannulae with Vent Line with Cortiva™ BioActive Surface	CB20012	III	NA	7, 13, 17	G7 039709 0999 REV.01

Attachment B to the Declaration of Conformity DC1066: Applicable Standards

The below mentioned Standards apply to all the product(s) mentioned on the applicable CE Mark certificate.

Standard Number	Description
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes.

Refer to TF-0066 for the list of applied standards.

Title: Declaration of Conformity: Octopus® Evolution, Octopus® 4, Octopus® 4.3, and Octopus® Evo AS

REV	CO#	Description of Change
1A	CO10032007	Introduce new EU Declaration of Conformity specific to Octopus Evolution, Octopus 3, Octopus 4, Octopus 4.3, and Octopus Evo AS
1B	CO10048417	Update the QS Certificate, Conformity Assessment Route, Applicable Standard, and correct the EU classification on Attachment A.
1C	CO10065374	Update to QS Certificate and Cover sheet
1D	CO10132863	Update Quality Systems Certificate Number and Header Format. Remove Octopus 3- obsolete.
AA	RCH00060389	Update EC Quality System Certificate from G1 14 11 39709 0952 to G1 039709 1263 Rev. 00 Update ISO 13485 standard from 2012 to 2016 Update template and minor formatting changes
AB	RCH00079924	Updated EC Quality System Certificate from G1 039709 1263 Rev. 00 to G1 039709 1304 Rev. 00

EC DECLARATION OF CONFORMITY

Manufacturer:	Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN 55432 United States of America
EC Representative	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Design Facility	Medtronic Perfusion Systems 7611 Northland Drive Minneapolis, MN 55428 USA
Product:	See **Attachment A**
Classification, Rules:	Class IIa, Rule 7
Conformity Assessment Route	Annex II (excluding Section 4)

I, the undersigned, hereby declare that the Medical Devices specified above and provided with the CE marking, meet the provisions of Council Directive 93/42/EEC of 14 June 1993 as amended by 2007/47/EC which apply to them. This declaration is supported by the Certificates according to the provisions of relevant Annex of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Standards Applied:	See **Attachment B**
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstr 65 D-80339 München, Germany
Identification Number:	0123
EC Quality System Certificate:	G1 039709 1304 Rev. 00
Place of Issue:	Minneapolis, Minnesota USA

Authorized Signature:

Name: Michael Green
Title: Senior Manager, Regulatory Affairs
Date: 22 MAY 2020

Attachment A to Declaration of Conformity DC1115: Products

This attachment specifies the Class IIa products included in the above referenced Declaration of Conformity.

A.) Octopus® Evolution
B.) Octopus® 4
C.) Octopus® 4.3
D.) Octopus® Evo AS

A.) Octopus® Evolution

Device Description	Model Number	Variant(s)	MDD Rule	QS Certificate
Octopus® Evolution Tissue Stabilizer	TS2000	NA	7	G1 039709 1304 Rev. 00

B.) Octopus® 4

Device Description	Model Number	Variant(s)	MDD Rule	QS Certificate
Octopus® 4 Tissue Stabilizer	29400	NA	7	G1 039709 1304 Rev. 00

C.) Octopus® 4.3

Device Description	Model Number	Variant(s)	MDD Rule	QS Certificate
Octopus® 4.3 Tissue Stabilizer	29403	NA	7	G1 039709 1304 Rev. 00

D.) Octopus® Evo AS

Device Description	Model Number	Variant(s)	MDD Rule	QS Certificate
Octopus® Evolution AS	TS2500	NA	7	G1 039709 1304 Rev. 00

Attachment B to the Declaration of Conformity DC1115: Applicable Standards

The below mentioned Standards apply to all the product(s) mentioned on the applicable CE Mark certificate.

Standard Number	Description
EN ISO 13485: 2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes.

For product specific standards refer to TF-0115 Essential Requirements Checklist for the product.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 039709 1304 Rev. 00

Manufacturer:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Product Category(ies):

- **Autotransfusion Systems and Associated Disposables**
- **Centrifugal Blood Pumps**
- **Bio-Console Drive Units**
- **Flow Monitoring Systems**
- **Bio-Cal Blood Temperature Controller**
- **Temperature Monitoring Systems and Associated Disposables**
- **Blood Monitoring Systems**
- **Cardioplegia Delivery Systems**
- **Disposable Blood Handling Devices used for Open Heart Surgery**
- **Arterial Filters**
- **Oxygenators including Heat Exchangers, with and without Cardiotomy Reservoirs**
- **Cardiotomy Venous Reservoirs**
- **Venous Reservoir Bags**
- **Perfusion Equipment and Disposable Perfusion Devices**
- **Disposable Medical Devices for Drainage Systems**
- **Disposable Medical Devices for use in Extracorporeal Support: Cardioplegia, Cannulae, Catheters, Venting, Suction**
- **Pressure Display System & related accessories of class IIa**
- **Tissue Positioning/Stabilizing Devices**
- **Surgical Site Clearing Devices**
- **Intravascular Shunts**
- **Surgical Retractors**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72157211

Valid from: 2020-04-29
Valid until: 2024-05-26

Date, 2020-04-29

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany