EC CERTIFICATE

Number: **2028431CE06**

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III and Devices in Class I in sterile conditions and sterilised systems or procedure packs)

Manufacturer:

ZOLL Circulation, Inc.

2000 Ringwood Avenue
San Jose, CA 95131
United States Of America

For the product category(ies)

Heat Exchange Control Units and Start up Kits

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents that form the basis of this certificate:

Certification Notice 2028431CN, initially dated 26 November 2003
Addendum, initially dated 22 September 2009

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection, that covers the aspects of manufacture concerned with securing and maintaining sterile conditions, for the above mentioned product category in accordance to the provisions of Annex II Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory.
The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation of the products concerned and the assessments performed, are stated in the Certification Notice, which forms an integrative part of this certificate.

This certificate is valid until: **26 May 2024**
Issued for the first time: 22 September 2009
Revised: 17 January 2014
Reissued: 1 December 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

Digitally signed by Ceaicovschi Tudor
Date: 2024.02.21 10:42:37 EET
Reason: MoldSign Signature
Location: Moldova

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

ADDENDUM

Belonging to certificate: **2028431CE06**

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Heat Exchange Control Units and Start up Kits

Issued to:

ZOLL Circulation, Inc.
2000 Ringwood Avenue
San Jose, CA 95131
United States Of America

This certificate covers the following product(s):

- CoolGard 3000 (Class IIb)
- ThermoGard XP (Class IIb)
- CoolGard / ThermoGard Start-up Kit (Class I, sterile)

Initial date: 22 September 2009
Revision date: 22 November 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

EC DESIGN-EXAMINATION CERTIFICATE

Number: **2028431DE07**

Directive 93/42/EEC on Medical devices, Annex II (4)
(Devices in Class III)

Manufacturer:
Zoll Circulation, Inc.
2000 Ringwood Avenue
San Jose, CA 95131
United States Of America

For the product(s)

Intravascular Temperature Management Catheters

Documents that form the basis of this certificate:

Certification Notice 2028431CN, initially dated 26 November 2003
Addendum, initially dated 16 February 2020

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. Additionally, DEKRA hereby declares that the manufacturer fulfils the relevant provisions as specified in Annex I of Commission Regulation 722/2012 of 8 August, 2012 concerning medical devices manufactured utilising tissue of animal origin.
The necessary information and the reference to the relevant documentation of the products concerned and the examinations and assessments performed are stated in the Certification Notice, which forms an integrative part of this certificate.

This certificate is valid until: **26 May 2024**
Issued for the first time: 16 February 2020

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

ADDENDUM

Belonging to certificate: **2028431DE07**

EC DESIGN-EXAMINATION
MEDICAL DEVICES

Intravascular Temperature Management Catheters

Issued to:

Zoll Circulation, Inc.
2000 Ringwood Avenue
San Jose, CA 95131
United States Of America

This certificate covers the following product(s):

- Cool Line catheter kits
  - CL 2295AE
  - CL 2295CO
- ICY catheter kits
  - IC-3893 AE
  - IC-3893 CO
- Quattro catheter kits
  - IC-4593 AE
  - IC-4593 CO
- Solex 7 catheter kits
  - SL 2593 AE
  - SL 2593 CO

Initial date: 16 February 2020

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

CERTIFICATE

Number: **3821343**

The management system of:

ZOLL Circulation, Inc.

2000 Ringwood Avenue
San Jose, CA 95131-1728
United States of America

including the implementation meets the requirements of the standard:

ISO 13485:2016
EN ISO 13485:2016

Scope:
Design, Development, Manufacture, Distribution and Servicing of automated chest compressors for resuscitation and intravascular heating/cooling systems for management of core body temperature

Design, Development, Manufacture and Distribution of intravascular heating/cooling system catheters and intravascular heating/cooling system circuitry allowing connection of control units to the centralized patient monitoring system for management of core body temperature

Certificate expiry date: **1 December 2025**
Certificate effective date: 1 December 2022
Certified since: 7 December 2018

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M.A. McKenzie
Certification Manager

MGMT. SYS. RvA C 589

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra.nl Company registration 09085396

CERTIFICATE

Number: **3825099**

The management system of:

ZOLL Circulation, Inc.

2000 Ringwood Avenue
San Jose, CA 95131-1728
United States of America

Manufacturer Facility Identifier F004123

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Australia:	Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil:	RDC ANVISA n. 665/2022, 551/2021 and and 67/2009
Canada:	Medical Devices Regulations - Part 1- SOR 98/282
Japan:	MHLW Ministerial Ordinance 169 and Article 4 to Article 68
United States:	21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

Scope:
Design, Development, Manufacture, Distribution and Servicing of automated chest compressors for resuscitation and intravascular heating/cooling systems for management of core body temperature

Design, Development, Manufacture and Distribution of intravascular heating/cooling system catheters and intravascular heating/cooling system circuitry allowing connection of control units to the centralized patient monitoring system for management of core body temperature

Certificate expiry date: **2025-12-01**
Certificate effective date: 2022-12-01
Certified since: 2019-12-01

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M.A. McKenzie
Certification Manager

The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
https:/www.dekra-product-safety.com/en/certified-organizations

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Declaration of Conformity

Manufacturer: ZOLL Circulation, Inc.
2000 Ringwood Avenue
San Jose, CA 95131, USA

Product Description: ZOLL Intravascular Heat Exchange Catheters (See attached product List)
Applicable Directive: Council Directive 93/42/EEC Concerning Medical Devices

Classification: Heparin Coated Catheters: Class III (MDD Annex IX, Rules 7, 13, and 17)
Non-Heparin Coated Catheters: Class III (MDD Annex IX, Rule 7)

Route to Conformity: MDD Annex II

Notified Body: DEKRA Certification B.V. (CE 0344)
Meander 1051, Postbus 5185
6825 MJ, 6802 ED
Arnhem, The Netherlands

EC REP — Emergo Europe
Prinsessegracht 20
2514 AP The Hague, The Netherlands

CH REP — ZOLL Medical Switzerland A.G. Bahnhofstrasse 20 6300, Zug Switzerland

Certificates: CE Marking of Conformity Certificate: # 2028431CE05
EC Design Examination Certificates: # 2028431DE07 (Icy, Cool Line, Quattro and Solex 7 Catheter), Quality System Certificate: # 3821343 (ISO/EN ISO 13485:2016), Quality System Certificate: # 3825099 (MDSAP ISO 13458:2016)

Declaration: We hereby declare that the products listed conform to the EC Council Directive 93/42/EEC Concerning Medical Devices and Switzerland's Medical Device Ordinance (MedDO) of 1 July 2020. This is based on the Certificates listed above in accordance with Annex II of the EC-Directive provided by DEKRA Certification B.V.

Chelmsford, MA, USA
Place of Signature

Elizabeth Haines (Dec 16, 2021 15:11 EST)
Elizabeth Haines
Senior Director, Regulatory Affairs

Dec 16th, 2021
Date

Attachment – Product List

ZOLL Intravascular Heat Exchange Catheters (Class III)

Product Name	Model Number	Catalog Number	Initial Certification Date
Cool Line Catheters with Custom Luers			
Cool Line Intravascular Heat Exchange Catheter Kit with SurModics Heparin Coating	CL-2295AE	8700-0781-40	August 18, 2015
Cool Line Intravascular Heat Exchange Catheter Kit with SurModics Hydrophilic (Non-Heparin) Coating	CL-2295AE	8700-0786-40	August 18, 2015
Cool Line Intravascular Heat Exchange Catheter Kit with SurModics Heparin Coating, CO kit	CL-2295CO	8700-0781-14	August 18, 2015
Icy Catheters with Custom Luers			
Icy Intravascular Heat Exchange Catheter Kit with SurModics Heparin Coating	IC-3893AE	8700-0782-40	August 18, 2015
Icy Intravascular Heat Exchange Catheter Kit with SurModics Hydrophilic (Non-Heparin) Coating	IC-3893AE	8700-0787-40	August 18, 2015
Icy Intravascular Heat Exchange Catheter Kit with SurModics Heparin Coating, CO kit	IC-3893CO	8700-0782-14	August 18, 2015
Quattro Catheters with Custom Luers			
Quattro Intravascular Heat Exchange Catheter Kit with SurModics Heparin Coating	IC-4593AE	8700-0783-40	August 18, 2015
Quattro Intravascular Heat Exchange Catheter Kit with SurModics Hydrophilic (Non-Heparin) Coating	IC-4593AE	8700-0788-40	August 18, 2015
Quattro Intravascular Heat Exchange Catheter Kit with SurModics Heparin Coating, CO kit	IC-4593CO	8700-0783-14	August 18, 2015
Solex 7 Catheters with Custom Luers			
Solex 7 Intravascular Heat Exchange Catheter Kit with SurModics Heparin Coating	SL-2593AE	8700-0793-40	November 17, 2015
Solex 7 Intravascular Heat Exchange Catheter Kit with SurModics Heparin Coating, CO kit	SL-2593CO	8700-0793-14	November 17, 2015

Revision History

Rev.	Description	Originator	Effective Date
01	Initial Release	R. Kimura	9/18/2015
02	Added Solex 7 Catheter (8700-0793-40), corrected part number for Solex CO kit with standard Luers, corrected header to match standard ZOLL format.	J. Gendler	11/20/2015
03	Corrected Solex 7 CO kit model number from erroneous "SL-2593AE" to "SL-2593CO."	J. Gendler	5/17/2016
04	• Revised Emergo Europe's Address • Removed Standard Luer CO Model kits for Icy, Cool Line, Quattro and Solex Catheters from products list.	Harini Raghavan	6/1/2018
05	• Updated reference to renewed ISO/EN ISO 13485:2016 Certificate • Added reference to MDSAP ISO 13485:2016 Certificate • Deleted reference to Standard Luer Catheters and Solex 2 Catheter	Harini Raghavan	11/26/2019
06	• Added reference the consolidated Design Examination Certificate for all catheters (2028431DE07) • Deleted reference to old Design Examination Certificates for each catheter (2028431DE02, 2028431DE03 and 2028431DE04)	Harini Raghavan	02/08/2020
07	• Added Legal Importer symbol and address • Replace text for AR with the EC AR symbol	Harini Raghavan	05/14/2021
08	• Corrected document header per ZOLL Circulation format • Corrected Document history block to add document release date for revision 6 and 7.	Harini Raghavan	06/04/2021
09	• Addition of Swiss authorized representative (CH REP) and language added to reflect compliance to Swiss MEDDO	Riki Chaudhary	See Signature Page

01 EDC-2837 Rev. 09 Declaration of Conformity IVTM Catheters - Final

Final Audit Report 2021-12-16

Created:	2021-12-16
By:	Riki Chaudhary (rchaudhary@zoll.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA2yHOsJE4E7F611tldhxPBfAzXd7v7V2x

"01 EDC-2837 Rev. 09 Declaration of Conformity IVTM Catheters - Final" History

Document created by Riki Chaudhary (rchaudhary@zoll.com)
2021-12-16 - 7:38:18 PM GMT

Document emailed to Elizabeth Haines (ehaines@zoll.com) for signature
2021-12-16 - 7:38:45 PM GMT

Email viewed by Elizabeth Haines (ehaines@zoll.com)
2021-12-16 - 8:11:02 PM GMT

Document e-signed by Elizabeth Haines (ehaines@zoll.com)
Signature Date: 2021-12-16 - 8:11:12 PM GMT - Time Source: server

Agreement completed.
2021-12-16 - 8:11:12 PM GMT

Signatures

Harmon, Hal

Document ID: EDC-2837
Revision: 09
Electronically signed by Harmon, Hal
Title: VP and General Manager
Date: 12/20/2021 1:05:26 PM
Reason: Approval of Document

Creech, Jeffrey

Document ID: EDC-2837
Revision: 09
Electronically signed by Creech, Jeffrey
Title: VP, Clinical Affairs
Date: 12/20/2021 1:58:59 PM
Reason: Approval of Document

Haines, Elizabeth

Document ID: EDC-2837
Revision: 09
Electronically signed by Haines, Elizabeth
Title: Director Regulatory Affairs - Chelmsford
Date: 12/20/2021 1:59:23 PM
Reason: Approval of Document

Wilburn, Olivia

Document ID: EDC-2837
Revision: 09
Electronically signed by Wilburn, Olivia
Title: VP, Medical Affairs
Date: 12/21/2021 8:25:06 AM
Reason: Approval of Document

Chaudhary, Riki

Document ID: EDC-2837
Revision: 09
Electronically signed by Chaudhary, Riki
Title: Regulatory Affairs Specialist – Chelmsford, MA office
Date: 12/21/2021 11:35:49 AM
Reason: Approval of Document

Chaudhary, Riki

Document ID: EDC-2837
Revision: 09
Electronically signed by Chaudhary, Riki
Title: Regulatory Affairs Specialist – Chelmsford, MA office
Date: 12/21/2021 11:35:49 AM
Reason: Approval of Document

Declarația de conformitate

Producător: ZOLL Circulation, Inc.
2000 Ringwood Avenue
San Jose, CA 95131,
SUA

Descriere produs: Consola de schimb de căldură intravasculară
Accesoriu de interfață pentru monitorul de spital (HMIA) Kit de pornire (SUK)
(A se vedea lista de produse anexată)

Directiva aplicabilă: Directiva 93/42/CEE a Consiliului privind dispozitivele medicale

Clasificare: Console: Clasa IIb (MDD Anexa IX, Regula 9) HMIA: Clasa IIa (MDD Anexa IX, Regula 2) Kit de pornire: Clasa Is (anexa IX, regula 1 la MDD).

Calea spre conformitate: MDD Anexa II

Organism notificat: DEKRA Certification B.V. (CE 0344)
Meander 1051, Postbus 5185
6825 MJ, 6802 ED, Arnhem, Țările de Jos

EC REP Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem, Țările de Jos

ZOLL International Holding B.V
Einsteinweg 8A, 6662 PW ELST, Țările de Jos

CH REP ZOLL Medical Switzerland A.G., Baarerstrasse 8, 6300, Zug Elveția

Certificate: Certificat de conformitate cu marcajul CE: # 2028431CE06
Certificatul sistemului de calitate: # 3821343 (ISO/EN ISO 13485:2016) Certificat de sistem de calitate: # 3825099 (MDSAP ISO 13458:2016)

Declarație: Prin prezenta declarăm că produsele enumerate sunt conforme cu Directiva 93/42/CEE a Consiliului CE privind dispozitivele medicale și cu Ordonanța privind dispozitivele medicale din Elveția (MedDO) din 1 iulie 2020. Această declarație se bazează pe certificatele enumerate mai sus, în conformitate cu anexa II la Directiva CE, furnizate de DEKRA Certification B.V.

San Jose, CA, SUA _____ 07/25/2023

Locul semnării Nazma Chaudhry Data
Director, Afaceri de reglementare
ZOLL Circulation, Inc.

Anexă - Lista de produse

Consolă de schimb de căldură intravasculară (clasa IIb), kit de pornire (clasa Is) și accesoriu de interfață pentru monitorul de spital (clasa IIa)

Număr de catalog	Număr de model	Descriere	Data certificării inițiale
8700-0650-XX*	TGXP	Consola de schimb de căldură intravasculară Thermogard XP®.	26 noiembrie 2003
8700-0652-40	HMIA	Accesoriu de interfață pentru monitoare de spital	26 noiembrie 2003
8700-0784-01	CG-500D	Kit de pornire, CG-500D cu Luers personalizate	18 august 2015
8700-0785-01	CG-500D EX	Kit de pornire, CG-500D EX cu Luers personalizate	18 august 2015
8700-0784-40	CG-500D	Kit de pornire, CG-500D EU cu Luers personalizate	18 august 2015
8700-0785-40	CG-500D EX	Kit de pornire, CG-500D EX EU cu Luers personalizate	18 august 2015
8700-000921-40	Casetă TL	Caseta Thermogard XP3, model TL (din kitul de cateter ICY)	12 martie 2019
8700-000919-40	Casetă TL	Caseta Thermogard XP3, model TL (din kitul de cateter Cool Line)	12 martie 2019
8700-000922-40	Casetă TL	Caseta Thermogard XP3, model TL (din kitul de cateter Quattro)	12 martie 2019
8700-000920-40	Casetă TL	Caseta Thermogard XP3, model TL (din kitul de cateter Solex)	12 martie 2019
8700-000929-40	Casetă TL	Caseta Thermogard XP3, model TL (din kitul de cateter ICY, pachet de 2)	12 martie 2019
8700-000930-40	Casetă TL	Cassetă Thermogard XP3, model TL (din kitul de cateter Cool Line, pachet de 2)	12 martie 2019
8700-000931-40	Casetă TL	Caseta Thermogard XP3, model TL (din kitul de catetere Quattro, pachet de 2)	12 martie 2019
8700-000932-40	Casetă TL	Caseta Thermogard XP3, model TL (din kitul de catetere Solex, pachet de 2)	12 martie 2019

Dispozitive care nu mai sunt fabricate, dar care beneficiază de asistență

Număr de catalog	Număr de model	Descriere	Data certificării inițiale
8700-0651-XX*	CG 3000	Consola de schimb de căldură intravasculară CoolGard 3000®	26 noiembrie 2003

*Intravascular Heat Exchange Console Variante lingvistice

Extensie număr de catalog ZOLL	Extensie a numărului de [illegible] ZOLL	Limba dispozitivului
-12	-002	Engleză, Euro
-27	-003	Daneză
-16	-004	Olandeză
-21	-005	Finlandeză
-02	-006	Franceză
-08	-007	Germană
-19	-008	Greacă
-11	-009	Italian
-18	-010	Portugheză
-10	-011	Spaniolă
-22	-012	Suedeză
-17	-014	Cehia
-04	-015	Poloneză
-29	-016	Rusă
-51	-017	Letonă

Istoricul revizuirii

Rev.	Descriere	Autor	Data intrării în
01	Lansarea inițială	R. Kimura	09/18/2015
02	Revizuirea adresei Emergo Europe	Harini Raghavan	06/4/2018
03	Revizuit pentru a include casetă TGXP 3, model TL	Harini Raghavan	04/5/2019
04	Referință actualizată la certificatul ISO/EN ISO 13485:2016 reînnoit Referință adăugată la certificatul MDSAP ISO	Harini Raghavan	11/26/2019
05	• A fost adăugat simbolul și adresa • importatorului legal. Înlocuirea textului	Harini Raghavan	05/14/2021
06	• Antetul documentului a fost corectat conform formatului ZOLL Circulation • Corectarea blocului istoric al documentului cu data publicării documentului pentru revizuirea 5	Harini Raghavan	06/07/2021
07	• Adăugarea reprezentantului autorizat elvețian (CH REP) și adăugarea unui text care să reflecte conformitatea cu MEDDO	Riki Chaudhary	12/21/2021
08	• S-au adăugat noi numere de piese pentru kitul de pornire fără configurația seringii BD de 20 ml (noi numere de piese: 8700-0784-40 și 8700-0785- 40). • A fost eliminat 8700-0666-01 și 8700-0667-01, vechiul kit de pornire, deoarece nu mai sunt fabricate și livrate. • Adăugat detalii privind importatorul UE (ZOLL International Holding B.V)	Riki Chaudhary	03/13/2023
09	• Adresele Emergo Europe și ZOLL Medical Switzerland au fost actualizate ca urmare a relocării acestora.	Riki Chaudhary	A se vedea pagina

Semnături

Creech, Jeffrey

Document ID: EDC-2838
Revizuire: 09
Semnat electronic de Creech, Jeffrey
Titlu: VP, Clinical Affairs
Data: 7/31/2023 12:30:56 PM
Motivul: Aprobarea documentului

Harmon, Hal

Document ID: EDC-2838
Revizuire: 09
Semnat electronic de Harmon, Hal
Titlu: Vicepreședinte și director general Data: 7/31/2023 1:34:21 PM
Motivul: Aprobarea documentului

Mitchell, Mark

Document ID: EDC-2838
Revizuire: 09
Semnat electronic de Mitchell, Mark
Titlu: VP, Cercetare și Dezvoltare
Data: 7/31/2023 5:00:35 PM
Motivul: Aprobarea documentului

Manning, Sean

Document ID: EDC-2838
Revizuire: 09
Semnat electronic de Manning, Sean
Titlu: Senior Manager, Regulatory Affairs
Data: 8/1/2023 6:27:36 AM
Motivul: Aprobarea documentului

Lam, Doug

Document ID: EDC-2838
Revizuire: 09
Semnat electronic de Lam, Doug
Titlu: Director, Quality & Regulatory Compliance
Data: 8/1/2023 10:50:53 AM
Motivul: Aprobarea documentului

Chaudhary, Riki

Document ID: EDC-2838
Revizuire: 09
Semnat electronic de Chaudhary, Riki
Titlu: Regulatory Affairs Specialist - Chelmsford, MA office
Data: 8/1/2023 10:59:58 AM
Motivul: Aprobarea documentului

ADDENDUM

Care aparține certificatului: **2028431CE061/1**

MARCAJ DE CONFORMITATE CE
DISPOZITIVE MEDICALE

Unități de control al schimbului de căldură și kituri de pornire

Eliberat pentru:

ZOLL Circulation, Inc.
2000 Ringwood Avenue
San Jose, CA 95131
Statele Unite ale Americii

Acest certificat se referă la următorul (următoarele) produs(e):

- CoolGard 3000 (clasa IIb)
- ThermoGard XP (clasa IIb)
- Kit de pornire CoolGard / ThermoGard (Clasa I, steril)

Data inițială: 22 septembrie 2009
Data revizuirii: 22 noiembrie 2019

DEKRA Certification B.V.

B.T.M. Holtus
Director general

J.A. van Vugt
Manager de certificare

DEKRA Certification B.V. este organismul notificat cu ID nr. 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, Țările de Jos T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com înregistrarea companiei 09085396

CERTIFICAT CE

Număr: **2028431CE06**

Sistem complet de asigurare a calității

Directiva 93/42/CEE privind dispozitivele medicale, anexa II, cu excepția (4)
(Dispozitive din clasa IIa, IIb sau III și dispozitive din clasa I în condiții de sterilitate și sisteme sau pachete de proceduri sterilizate)

Producător:

ZOLL Circulation, Inc.
2000 Ringwood Avenue
San Jose, CA 95131
Statele Unite ale Americii

Pentru categoria (categoriile) de produse

Unități de control al schimbului de căldură și kituri de pornire

DEKRA acordă dreptul de a utiliza numărul de identificare a organismului notificat CE ilustrat mai jos pentru a însoți marcajul de conformitate CE pentru produsele în cauză care sunt conforme cu documentația tehnică necesară și care îndeplinesc dispozițiile directivei CE care li se aplică:

0344

Documentele care stau la baza prezentului certificat:

Aviz de certificare 2028431CN, datat inițial la 26 noiembrie 2003 Addendum, datat inițial la 22 septembrie 2009

DEKRA declară prin prezenta că producătorul menționat mai sus îndeplinește dispozițiile relevante ale "Besluit Medische Hulpmiddelen", transpunerea în Țările de Jos a Directivei 93/42/CEE a Consiliului din 14 iunie 1993 privind dispozitivele medicale, inclusiv toate modificările ulterioare. Producătorul a pus în aplicare un sistem de asigurare a calității pentru proiectare, fabricație și inspecție finală, care acoperă aspectele de fabricație legate de asigurarea și menținerea condițiilor de sterilitate, pentru categoria de produse menționată mai sus, în conformitate cu dispozițiile anexei II la Directiva 93/42/CEE a Consiliului din 14 iunie 1993 și face obiectul unei supravegheri periodice. Pentru introducerea pe piață a dispozitivelor din clasa III este obligatoriu un certificat suplimentar de examinare CE a proiectului în conformitate cu anexa II punctul 4.
Informațiile necesare referitoare la sistemul de management al calității al producătorului, inclusiv instalațiile și trimiterile la documentația relevantă a produselor în cauză și evaluările efectuate, sunt menționate în avizul de certificare, care face parte integrantă din prezentul certificat.

Acest certificat este valabil până la: **26 mai 2024**
Eliberat pentru primadată: 22septembrie 2009
Revizuit: 17 ianuarie 2014
Reeditat: 1 decembrie 2019

DEKRA Certification B.V.

B.T.M. Holtus
Director general

J.A. van Vugt
Manager de certificare

TRADUCĂTOR AUTORIZAT DE MINISTERUL JUSTIȚIEI MIHAELA BALTĂ Aut.Nr. 9839 ROMÂNIA

DEKRA Certification B.V. este organismul notificat cu ID nr. 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, Țările de Jos T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com înregistrarea companiei 09085396

CERTIFICAT

Număr: **3821343**

Sistemul de management al:

ZOLL Circulation, Inc.

2000 Ringwood Avenue
San Jose, CA 95131-1728
Statele Unite ale Americii

inclusiv punerea în aplicare îndeplinește cerințele standardului:

ISO 13485:2016
EN ISO 13485:2016

Domeniul de aplicare:
Proiectarea, dezvoltarea, fabricarea, distribuția și întreținerea compresoarelor toracice automate pentru resuscitare și a sistemelor de încălzire/răcire intravasculară pentru gestionarea temperaturii corporale centrale.

Proiectarea, dezvoltarea, fabricarea și distribuția de cateteре pentru sistemul de încălzire/răcire intravasculară și de circuite pentru sistemul de încălzire/răcire intravasculară care să permită conectarea unităților de control la sistemul centralizat de monitorizare a pacientului pentru gestionarea temperaturii corpului central

Data de expirare a certificatului: **1 decembrie 2025**
Data de intrare în vigoare a certificatului: 1 decembrie 2022
Certificat din: 7 decembrie 2018

DEKRA Certification B.V.

B.T.M. Holtus
Director general

J.M.A. McKenzie
Manager de certificare

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, Țările de Jos T +31 88 96 83000 F +31 88 96 83100 www.dekra.nl Înregistrarea companiei 09085396

CERTIFICAT

Număr: **3825099**

Sistemul de management al:

ZOLL Circulation, Inc.

2000 Ringwood Avenue
San Jose, CA 95131-1728
Statele Unite ale Americii

Identificatorul de identificare a instalației producătorului F004123

Este în conformitate cu următoarele cerințe standard și de reglementare:

ISO 13485:2016

Australia:	Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule3 Part 1 (excluzând partea 1.6) - Procedura completă de asigurare a calității
Brazilia:	RDC ANVISA nr. 665/2022, 551/2021 și 67/2009
Canada:	Reglementări privind dispozitivele medicale - Partea 1 - SOR 98/282
Japonia:	MHLW Ordonanța ministerială 169 și articolul 4 până la articolul 68
Statele Unite ale Americii:	21 CFR 803, 21 CFR 806, 21 CFR 807 - Subpărțile A-D și 21 CFR 820.

Domeniul de aplicare:
Proiectarea, dezvoltarea, fabricarea, distribuția și întreținerea compresoarelor toracice automate pentru resuscitare și a sistemelor de încălzire/răcire intravasculară pentru gestionarea temperaturii corporale centrale.

Proiectarea, dezvoltarea, fabricarea și distribuția de catetere pentru sistemul de încălzire/răcire intravasculară și de circuite pentru sistemul de încălzire/răcire intravasculară care să permită conectarea unităților de control la sistemul centralizat de monitorizare a pacientului pentru gestionarea temperaturii corpului central

Data de expirare a	**2025-12-01**
Data intrării în vigoare a	2022-12-01
Certificată din:	2019-12-01

DEKRA Certification B.V.

B.T.M. Holtus
Director general

J.M.A. McKenzie
Manager de

TRADUCĂTOR AUTORIZAT DE MINISTERUL JUSTIȚIEI MIHAELA BALTĂ Aut. Nr. 9639 ROMÂNIA

Validarea valabilității acestui certificat poate fi verificată prin intermediul site-ului DEKRA, folosind următorul link: https:/www.dekra-product-safety.com/en/certified-organizations

DEKRA Certification B.V. este recunoscută în cadrul Programului de audit unic pentru dispozitive medicale.

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Declaration of Conformity

Manufacturer: ZOLL Circulation, Inc. 2000
Ringwood Avenue San Jose, CA
95131, USA

Product Description: ZOLL Intravascular Heat Exchange Catheters (See attached product List)

Applicable Directive: Council Directive 93/42/EEC Concerning Medical Devices

Classification: Heparin Coated Catheters: Class III (MDD Annex IX, Rules 7, 13, and 17)
Non-Heparin Coated Catheters: Class III (MDD Annex IX, Rule 7)

Route to Conformity: MDD Annex II

Notified Body: DEKRA Certification B.V. (CE 0344) Meander 1051,
Postbus 5185
6825 MJ, 6802 ED
Arnhem, The Netherlands

EC REP
Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

ZOLL International Holding B.V,
Einsteinweg 8A, 6662 PW ELST,
The Netherlands

CH REP
ZOLL Medical Switzerland A.G., Baarerstrasse 8, 6300, Zug Switzerland

Certificates: CE Marking of Conformity Certificate: # 2028431CE05
EC Design Examination Certificates: # 2028431DE07 (Icy, Cool Line, Quattro and Solex 7 Catheter), Quality System Certificate: # 3821343 (ISO/EN ISO 13485:2016), Quality System Certificate: # 3825099 (MDSAP ISO 13458:2016)

Declaration: We hereby declare that the products listed conform to the EC Council Directive 93/42/EEC Concerning Medical Devices and Switzerland's Medical Device Ordinance (MedDO) of 1 July 2020. This is based on the Certificates listed above in accordance with Annex II of the EC- Directive provided by DEKRA Certification B.V.

San Jose, CA, USA
Place of Signature

Nazma Chaudhry
Digitally signed by Nazma Chaudhry
Date: 2023.07.25 11:16:23 -07'00'

Nazma Chaudhry
Director, Regulatory Affairs
ZOLL Circulation, Inc.

07/25/2023
Date

Attachment – Product List

ZOLL Intravascular Heat Exchange Catheters (Class III)

Product Name	Model Number	Catalog Number	Initial Certification Date
Cool Line Catheters with Custom Luers			
Cool Line Intravascular Heat Exchange Catheter Kit with SurModics Heparin Coating	CL-2295AE	8700-0781-40	August 18, 2015
Cool Line Intravascular Heat Exchange Catheter Kit with SurModics Hydrophilic (Non-Heparin) Coating	CL-2295AE	8700-0786-40	August 18, 2015
Cool Line Intravascular Heat Exchange Catheter Kit with SurModics Heparin Coating, CO kit	CL-2295CO	8700-0781-14	August 18, 2015
Icy Catheters with Custom Luers			
Icy Intravascular Heat Exchange Catheter Kit with SurModics Heparin Coating	IC-3893AE	8700-0782-40	August 18, 2015
Icy Intravascular Heat Exchange Catheter Kit with SurModics Hydrophilic (Non-Heparin) Coating	IC-3893AE	8700-0787-40	August 18, 2015
Icy Intravascular Heat Exchange Catheter Kit with SurModics Heparin Coating, CO kit	IC-3893CO	8700-0782-14	August 18, 2015
Quattro Catheters with Custom Luers			
Quattro Intravascular Heat Exchange Catheter Kit with SurModics Heparin Coating	IC-4593AE	8700-0783-40	August 18, 2015
Quattro Intravascular Heat Exchange Catheter Kit with SurModics Hydrophilic (Non-Heparin) Coating	IC-4593AE	8700-0788-40	August 18, 2015
Quattro Intravascular Heat Exchange Catheter Kit with SurModics Heparin Coating, CO kit	IC-4593CO	8700-0783-14	August 18, 2015
Solex 7 Catheters with Custom Luers			
Solex 7 Intravascular Heat Exchange Catheter Kit with SurModics Heparin Coating	SL-2593AE	8700-0793-40	November 17, 2015
Solex 7 Intravascular Heat Exchange Catheter Kit with SurModics Heparin Coating, CO kit	SL-2593CO	8700-0793-14	November 17, 2015

Revision History

Rev.	Description	Originator	Effective Date
01	• Initial Release	R. Kimura	9/18/2015
02	• Added Solex 7 Catheter (8700-0793-40), corrected part number for Solex CO kit with standard Luers, corrected header to match standard ZOLL format.	J. Gendler	11/20/2015
03	• Corrected Solex 7 CO kit model number from erroneous "SL-2593AE" to "SL- 2593CO."	J. Gendler	5/17/2016
04	• Revised Emergo Europe's Address • Removed Standard Luer CO Model kits for Icy, Cool Line, Quattro and Solex Catheters from products list.	Harini Raghavan	6/1/2018
05	• Updated reference to renewed ISO/EN ISO 13485:2016 Certificate • Added reference to MDSAP ISO 13485:2016 Certificate • Deleted reference to Standard Luer Catheters and Solex 2 Catheter	Harini Raghavan	11/26/2019
06	• Added reference the consolidated Design Examination Certificate for all catheters (2028431DE07) • Deleted reference to old Design Examination Certificates for each catheter (2028431DE02, 2028431DE03 and 2028431DE04)	Harini Raghavan	02/08/2020
07	• Added Legal Importer symbol and address. • Replace text for AR with the EC AR symbol	Harini Raghavan	05/14/2021
08	• Corrected document header per ZOLL Circulation format • Corrected Document history block to add document release date for revision 6 and 7.	Harini Raghavan	06/04/2021
09	• Addition of Swiss authorized representative (CH REP) and language added to reflect compliance to Swiss MEDDO	Riki Chaudhary	12/21/2021
10	• Updated Emergo Europe and ZOLL Medical Switzerland address due to their relocation. • Added EU Importer details (ZOLL International Holding B.V)	Riki Chaudhary	See Signature Page

Signatures

Creech, Jeffrey

Document ID: EDC-2837
Revision: 10
Electronically signed by Creech, Jeffrey
Title: VP, Clinical Affairs
Date: 7/31/2023 12:30:50 PM
Reason: Approval of Document

Harmon, Hal

Document ID: EDC-2837
Revision: 10
Electronically signed by Harmon, Hal
Title: VP and General Manager
Date: 7/31/2023 1:34:10 PM
Reason: Approval of Document

Mitchell, Mark

Document ID: EDC-2837
Revision: 10
Electronically signed by Mitchell, Mark
Title: VP, Research & Development
Date: 7/31/2023 5:00:41 PM
Reason: Approval of Document

Manning, Sean

Document ID: EDC-2837
Revision: 10
Electronically signed by Manning, Sean
Title: Senior Manager, Regulatory Affairs
Date: 8/1/2023 6:27:11 AM
Reason: Approval of Document

Lam, Doug

Document ID: EDC-2837
Revision: 10
Electronically signed by Lam, Doug
Title: Director, Quality & Regulatory Compliance
Date: 8/1/2023 10:50:38 AM
Reason: Approval of Document

Chaudhary, Riki

Document ID: EDC-2837
Revision: 10
Electronically signed by Chaudhary, Riki
Title: Regulatory Affairs Specialist – Chelmsford, MA office
Date: 8/1/2023 10:59:51 AM
Reason: Approval of Document

Declaration of Conformity

Manufacturer: ZOLL Circulation, Inc.
2000 Ringwood Avenue
San Jose, CA 95131, USA

Product Description: Intravascular Heat Exchange Consoles
Hospital Monitor Interface Accessory (HMIA)
Start-Up Kit (SUK)
(See attached product list)

Applicable Directive: Council Directive 93/42/EEC Concerning Medical Devices

Classification: Consoles: Class IIb (MDD Annex IX, Rule 9)
HMIA: Class IIa (MDD Annex IX, Rule 2)
Start-Up Kit: Class Is (MDD Annex IX, Rule 1)

Route to Conformity: MDD Annex II

Notified Body: DEKRA Certification B.V. (CE 0344)
Meander 1051, Postbus 5185
6825 MJ, 6802 ED, Arnhem, The Netherlands

EC REP — Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem, The Netherlands

ZOLL International Holding B.V
Einsteinweg 8A, 6662 PW ELST, The Netherlands

CH REP — ZOLL Medical Switzerland A.G., Baarerstrasse 8, 6300, Zug Switzerland

Certificates: CE Marking of Conformity Certificate: # 2028431CE06
Quality System Certificate: # 3821343 (ISO/EN ISO 13485:2016)
Quality System Certificate: # 3825099 (MDSAP ISO 13458:2016)

Declaration: We hereby declare that the products listed conform to the EC Council Directive 93/42/EEC Concerning Medical Devices and Switzerland's Medical Device Ordinance (MedDO) of 1 July 2020. This is based on the Certificates listed above in accordance with Annex II of the EC-Directive provided by DEKRA Certification B.V.

Nazma Chaudhry

Digitally signed by Nazma Chaudhry
Date: 2023.07.25 11:18:35 -07'00'

San Jose, CA, USA
Place of Signature

Nazma Chaudhry
Director, Regulatory Affairs
ZOLL Circulation, Inc.

07/25/2023
Date

Attachment – Product List

Intravascular Heat Exchange Console (Class IIb), Start-Up Kit (Class Is) and Hospital Monitor Interface Accessory (Class IIa)

ZOLL Catalog Number	Model Number	Description	Initial Certification Date
8700-0650-XX*	TGXP	Thermogard XP® Intravascular Heat Exchange Console	November 26, 2003
8700-0652-40	HMIA	Hospital Monitor Interface Accessory	November 26, 2003
8700-0784-01	CG-500D	Start-up Kit, CG-500D with Custom Luers	August 18, 2015
8700-0785-01	CG-500D EX	Start-up Kit, CG-500D EX with Custom Luers	August 18, 2015
8700-0784-40	CG-500D	Start-up Kit, CG-500D EU with Custom Luers	August 18, 2015
8700-0785-40	CG-500D EX	Start-up Kit, CG-500D EX EU with Custom Luers	August 18, 2015
8700-000921-40	TL Cassette	Thermogard XP3 Cassette, TL Model (from ICY Catheter Kit)	March 12, 2019
8700-000919-40	TL Cassette	Thermogard XP3 Cassette, TL Model (from Cool Line Catheter Kit)	March 12, 2019
8700-000922-40	TL Cassette	Thermogard XP3 Cassette, TL Model (from Quattro Catheter Kit)	March 12, 2019
8700-000920-40	TL Cassette	Thermogard XP3 Cassette, TL Model (from Solex Catheter Kit)	March 12, 2019
8700-000929-40	TL Cassette	Thermogard XP3 Cassette, TL Model (from ICY Catheter Kit, 2 Pack)	March 12, 2019
8700-000930-40	TL Cassette	Thermogard XP3 Cassette, TL Model (from Cool Line Catheter Kit, 2 Pack)	March 12, 2019
8700-000931-40	TL Cassette	Thermogard XP3 Cassette, TL Model (from Quattro Catheter Kit, 2 Pack)	March 12, 2019
8700-000932-40	TL Cassette	Thermogard XP3 Cassette, TL Model (from Solex Catheter Kit, 2 Pack)	March 12, 2019

Devices no longer manufactured but supported

ZOLL Catalog Number	Model Number	Description	Initial Certification Date
8700-0651-XX*	CG 3000	CoolGard 3000® Intravascular Heat Exchange Console	November 26, 2003

***Intravascular Heat Exchange Console Language Variants**

ZOLL Catalog Number Extension	ZOLL Part Number Extension	Device Language
-12	-002	English, Euro
-27	-003	Danish
-16	-004	Dutch
-21	-005	Finnish
-02	-006	French
-08	-007	German
-19	-008	Greek
-11	-009	Italian
-18	-010	Portuguese
-10	-011	Spanish
-22	-012	Swedish
-17	-014	Czech
-04	-015	Polish
-29	-016	Russian
-51	-017	Latvian

Revision History

Rev.	Description	Originator	Effective Date
01	Initial Release	R. Kimura	09/18/2015
02	Revised the Address of Emergo Europe	Harini Raghavan	06/4/2018
03	Revised to Include TGXP 3 Cassette, TL Model	Harini Raghavan	04/5/2019
04	Updated reference to renewed ISO/EN ISO 13485:2016 Certificate Added reference to MDSAP ISO 13485:2016 Certificate	Harini Raghavan	11/26/2019
05	• Added Legal Importer symbol and address. • Replace text for AR with the EC AR symbol	Harini Raghavan	05/14/2021
06	• Corrected document header per ZOLL Circulation format • Corrected Document history block with document release date for revision 5	Harini Raghavan	06/07/2021
07	• Addition of Swiss authorized representative (CH REP) and language added to reflect compliance to Swiss MEDDO	Riki Chaudhary	12/21/2021
08	• Added New Part numbers for the Start-up kit with no 20 ml BD Syringe configuration (New P/Ns: 8700-0784-40 and 8700-0785-40) • Removed 8700-0666-01 and 8700-0667-01 old Start-up kit P/Ns as they are no longer manufactured and shipped. • Added EU Importer details (ZOLL International Holding B.V)	Riki Chaudhary	03/13/2023
09	• Updated Emergo Europe and ZOLL Medical Switzerland address due to their relocation.	Riki Chaudhary	See Signature Page

Signatures

Creech, Jeffrey

Document ID: EDC-2838
Revision: 09
Electronically signed by Creech, Jeffrey
Title: VP, Clinical Affairs
Date: 7/31/2023 12:30:56 PM
Reason: Approval of Document

Harmon, Hal

Document ID: EDC-2838
Revision: 09
Electronically signed by Harmon, Hal
Title: VP and General Manager
Date: 7/31/2023 1:34:21 PM
Reason: Approval of Document

Mitchell, Mark

Document ID: EDC-2838
Revision: 09
Electronically signed by Mitchell, Mark
Title: VP, Research & Development
Date: 7/31/2023 5:00:35 PM
Reason: Approval of Document

Manning, Sean

Document ID: EDC-2838
Revision: 09
Electronically signed by Manning, Sean
Title: Senior Manager, Regulatory Affairs
Date: 8/1/2023 6:27:36 AM
Reason: Approval of Document

Lam, Doug

Document ID: EDC-2838
Revision: 09
Electronically signed by Lam, Doug
Title: Director, Quality & Regulatory Compliance
Date: 8/1/2023 10:50:53 AM
Reason: Approval of Document

Chaudhary, Riki

Document ID: EDC-2838
Revision: 09
Electronically signed by Chaudhary, Riki
Title: Regulatory Affairs Specialist – Chelmsford, MA office
Date: 8/1/2023 10:59:58 AM
Reason: Approval of Document

EC CERTIFICATE

Number: **2028431CE05**

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

ZOLL Circulation, Inc.

2000 Ringwood Avenue
San Jose, CA 95131
United States Of America

For the product category(ies)

Intravascular Temperature Management Catheters

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents that form the basis of this certificate:

Certification Notice 2028431CN, initially dated 26 November 2003
Addendum, initially dated 22 September 2009

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation of the products concerned and the assessments performed, are stated in the Certification Notice, which forms an integrative part of this certificate.

This certificate is valid until: **26 May 2024**
Issued for the first time: 22 September 2009
Revised: 17 January 2014
Reissued: 1 December 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

ADDENDUM

Belonging to certificate: **2028431CE05**

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Intravascular Temperature Management Catheters

Issued to:

ZOLL Circulation, Inc.
2000 Ringwood Avenue
San Jose, CA 95131
United States Of America

This certificate covers the following product(s):

Cool Line Catheters (Class III)
- CL 2295 AE
- CL 2295 CO

ICY Catheters (Class III)
- IC-3893 AE
- IC-3893 CO

Quattro Catheters (Class III)
- IC-4593 AE
- IC-4593 CO

Solex Catheters (Class III)
- SL 2593 AE
- SL 2593 CO

Initial date: 22 September 2009
Revision date: 22 November 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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