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	DOCUMENT ID: EDC-2837	DECLARATION OF CONFORMITY – ZOLL INTRAVASCULAR HEAT EXCHANGE CATHETERS

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



Emergo Europe
 Westervoortsedijk 60
 6827 AT Arnhem
 The Netherlands



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



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**

Nazma Chaudhry
 Director, Regulatory Affairs
 ZOLL Circulation, Inc.

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

07/25/2023

Date

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DOCUMENT ID:
EDC-2837

DECLARATION OF CONFORMITY – ZOLL INTRAVASCULAR HEAT EXCHANGE CATHETERS

PAGE:
2 OF 3

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

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**DECLARATION OF CONFORMITY – ZOLL INTRAVASCULAR HEAT
EXCHANGE CATHETERS**

PAGE:
3 OF 3

Revision History

Rev.	Description	Originator	Effective Date
01	<ul style="list-style-type: none">Initial Release	R. Kimura	9/18/2015
02	<ul style="list-style-type: none">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	<ul style="list-style-type: none">Corrected Solex 7 CO kit model number from erroneous “SL-2593AE” to “SL- 2593CO.”	J. Gendler	5/17/2016
04	<ul style="list-style-type: none">Revised Emergo Europe’s AddressRemoved Standard Luer CO Model kits for Icy, Cool Line, Quattro and Solex Catheters from products list.	Harini Raghavan	6/1/2018
05	<ul style="list-style-type: none">Updated reference to renewed ISO/EN ISO 13485:2016 CertificateAdded reference to MDSAP ISO 13485:2016 CertificateDeleted reference to Standard Luer Catheters and Solex 2 Catheter	Harini Raghavan	11/26/2019
06	<ul style="list-style-type: none">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	<ul style="list-style-type: none">Added Legal Importer symbol and address.Replace text for AR with the EC AR symbol	Harini Raghavan	05/14/2021
08	<ul style="list-style-type: none">Corrected document header per ZOLL Circulation formatCorrected Document history block to add document release date for revision 6 and 7.	Harini Raghavan	06/04/2021
09	<ul style="list-style-type: none">Addition of Swiss authorized representative (CH REP) and language added to reflect compliance to Swiss MEDDO	Riki Chaudhary	12/21/2021
10	<ul style="list-style-type: none">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
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Title: Regulatory Affairs Specialist – Chelmsford, MA office
Date: 8/1/2023 10:59:51 AM
Reason: Approval of Document

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	DOCUMENT ID: EDC-2838	DECLARATION OF CONFORMITY – INTRAVASCULAR HEAT EXCHANGE CONSOLES (COOLGARD 3000 AND THERMOGARD XP), HOSPITAL MONITOR INTERFACE ACCESSORY (HMIA), AND START-UP KIT (SUK)

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



Emergo Europe
 Westervoortsedijk 60
 6827 AT Arnhem, The Netherlands



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



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



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**DOCUMENT ID:
EDC-2838**

DECLARATION OF CONFORMITY – INTRAVASCULAR HEAT EXCHANGE CONSOLES (COOLGARD 3000 AND THERMOGARD XP), HOSPITAL MONITOR INTERFACE ACCESSORY (HMIA), AND START-UP KIT (SUK)

**PAGE:
2 OF 3**

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



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DECLARATION OF CONFORMITY – INTRAVASCULAR HEAT EXCHANGE CONSOLES (COOLGARD 3000 AND THERMOGARD XP), HOSPITAL MONITOR INTERFACE ACCESSORY (HMIA), AND START-UP KIT (SUK)

**PAGE:
3 OF 3**

***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	<ul style="list-style-type: none"> Added Legal Importer symbol and address. Replace text for AR with the EC AR symbol 	Harini Raghavan	05/14/2021
06	<ul style="list-style-type: none"> Corrected document header per ZOLL Circulation format Corrected Document history block with document release date for revision 5 	Harini Raghavan	06/07/2021
07	<ul style="list-style-type: none"> Addition of Swiss authorized representative (CH REP) and language added to reflect compliance to Swiss MEDDO 	Riki Chaudhary	12/21/2021
08	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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
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Product Service

Certificate

No. Q5 079546 0029 Rev. 02

Holder of Certificate: **ZOLL Medical Corporation**
269 Mill Road
Chelmsford MA 01824-4105
USA

Certification Mark:



Scope of Certificate: **Design and Development, Production, and Servicing and Distribution of Defibrillators, External Pacemakers, Multi-parameter Monitoring Systems, Adapters, Cables, Leads, Electrodes, Probes, Sensors, Ventilators with Patient Breathing Circuits and Ventilator Accessories, Aspirators, Intrathoracic Pressure Regulation (IPR) Devices for the Areas of Cardiac Resuscitation, Critical Care and Vital Signs Monitoring**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 079546 0029 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_079546_0029_Rev.02)

Report No.: 721014256

Valid from: 2026-03-16

Valid until: 2027-06-01

Date, 2026-03-16

Christoph Dicks
Head of Certification/Notified Body



Product Service

Certificate

No. Q5 079546 0029 Rev. 02

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **ZOLL Medical Corporation**
269 Mill Road, Chelmsford MA 01824-4105, USA

Design and Development, Production, Quality Control, Customer
Service

ZOLL Medical Corporation
271 Mill Road, Chelmsford MA 01824-4105, USA

Quality & Regulatory Affairs, Warehousing, and Servicing

ZOLL Medical Corporation
38 Upton Dr, Wilmington MA 01887, USA

Receiving, Incoming Inspection, Warehousing of raw materials and
finished goods, Final Product Kitting and Distribution activities

COOL LINE[®]

Intravascular Heat Exchange Catheter Kit
with central venous infusion capabilities (3 lumens)

REF 8700-0781-01
(CL-2295)



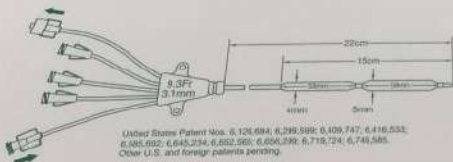
ZOLL

ZOLL Circulation, Inc.
2099 Ringwood Avenue
San Jose, CA 95131 USA
t: +1-408-541-2140
Reorder USA only: +1-978-421-9655

COOL LINE[®]

Intravascular Heat Exchange Catheter Kit
with central venous infusion capabilities (3 lumens)

REF 8700-0781-01
(CL-2295)



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Reorder USA only: +1-978-421-9655



REF 8700-0782-01
(IC-3893)

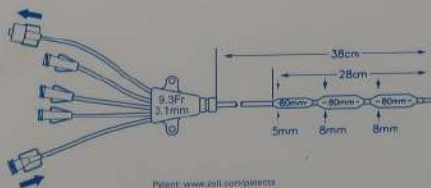
ICY[®]

Intravascular Heat Exchange Catheter Kit

with central venous infusion capabilities (3 lumens)



FEMORAL VEIN INSERTION ONLY



LOT 77727 2018-12-17



(01)00849111075237(17)181217(10)77727



Consult
instructions for use



Do not
inject



Do not
insertion



MR Conditional



Store between
20°C and 25°C



Sterilized using
ethylene oxide



10004-002 Rev. 7

ZOLL

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San Jose, CA 95131 USA
t: +1-408-541-2140
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REF 8700-0791-01
(IC-4593)

Premium Access Kit

QUATTRO[®]

Intravascular Heat Exchange Catheter Kit

with central venous infusion capabilities (3 lumens)

QUATTRO[®] Intravascular Heat Exchange Catheter Kit with central venous infusion capabilities (3 lumens)

Kit de sonda intravascular de intercambio de calor con capacidad de perfusión venosa central QUATTRO[®] (3 lúmenes)

Kit de sonda intravascular e de troca térmica QUATTRO[®] com capacidade de perfusão venosa central (3 lúmenes)

Intravaskulärer Wärmeaustauscher-Katheter-Kit mit zentraler Veneninfusionsfähigkeiten (3 Lumina)

QUATTRO[®] intravaskulärer Wärmeaustauscher-Katheter-Kit mit zentraler Veneninfusionsfähigkeiten (3 Lumina)

Kit sonda per scambio di calore intravascolare QUATTRO[®] con funzionalità di infusione venosa centrale (3 lumen)

QUATTRO[®] intravaskulärer Wärmeaustauscher-Katheter-Kit mit zentraler Veneninfusionsfähigkeiten (3 Lumina)

QUATTRO[®] intravaskulärer Wärmeaustauscher-Katheter-Kit mit zentraler Veneninfusionsfähigkeiten (3 Lumina)

Kateter za intravaskularni izmjenu toplote QUATTRO[®] s mogućnošću perifusije u središnju vensku strukturu (3 lumen)

Intravaskulärer Katheter QUATTRO[®] e sonda de calor e infusión central (3 lúmenes)

QUATTRO[®] intravaskulärer Wärmeaustauscher-Katheter-Kit mit zentraler Veneninfusionsfähigkeiten (3 Lumina)

Conjunto de Cateter Intravascular de Intercambio de Calor QUATTRO[®] con capacidades de perfusión venosa central (3 lúmenes)

Quattrotätter QUATTRO[®] - lämpösiirtokätkä, joka voi myös keskivaskulaariseen infuusiioon (3 lumen)

Overstik intravaskulær varmeutvekslingskatheter QUATTRO[®] e sonda med sentral venet infusjonskapasitet (3 lumen)

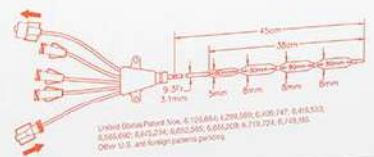
Perivaskulær varmeutvekslingskatheter med sentral venet infusjonskapasitet (3 lumen)

Zoll Intravaskulær Varmutvekslingskatheter-Kit med sentral venet infusjonskapasitet (3 lumen)

QUATTRO[®] intravaskulær varmeutvekslingskatheter med sentral venet infusjonskapasitet (3 lumen)

⚠ FEMORAL VEIN INSERTION ONLY

LOT 60434 2017-09-21
01700848111075803171709211060434



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Indicated for use
STERILEFO
Sterilized using ethylene oxide
From 1°C to 15°C
From 10°C to 25°C

RX ONLY

10360100-1

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