

**EC DECLARATION OF CONFORMITY  
FOR MEDICAL DEVICES**

acc. to Directive 93/42/EEC on Medical Devices

**Name and Address of the Manufacturer:** Datascope Corp.  
1300 MacArthur Blvd.,  
Mahwah, NJ 07430USA

**Name and Address of the Authorised Representative:** MAQUET Critical Care AB  
Rontgenvagen 2  
171 54 Solna, Sweden

On our sole responsibility, we hereby declare that the product(s)

**Product Description:** Cardiosave Intra-Aortic Balloon Pump  
and its accessories  
(Hybrid and Rescue model)

**Product-No.:** Refer to Appendix A of this document

**Classification** (acc. to Annex IX of MOD): Class IIb, Rule 9, Active Device

comply with the relevant provisions of the following Directive(s):

**Directive 93/42/EEC on Medical Devices**

**Notified Body:** TUV SUD Product Service GmbH  
Ridlerstraße 65  
80339 Munich  
Germany

**Conformity Assessment Procedure:** acc. to Annex II excluding (4) of Directive  
93/42/EEC

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**Directive 2011/65/EU on the restriction of the use of certain substances in electrical and electronic equipment**

**Directive 2010/35/EU of the European Parliament And of The Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC**

**Directive 2014/68/EU on Pressure Equipment** *(Not applicable)*

This declaration of conformity is valid from date of issue until the expiration date of the certificate(s) issued by the notified body.

Wayne NJ, 14 December, 2021



**Susan Eichler-Huston,**  
Senior Director of Regulatory Affairs  
Datascope Corp.

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## Appendix A

The products can be delivered in the following variants:

Product Description	Product-No.
<u>Cardiosave Intra-aortic Balloon Pump (Hybrid model)</u>	0998-00-0800-31
<u>Cardiosave Intra-aortic Balloon Pump (Hybrid model)</u>	0998-00-0800-32
<u>Cardiosave Intra-aortic Balloon Pump (Hybrid model)</u>	0998-00-0800-33
<u>Cardiosave Intra-aortic Balloon Pump (Hybrid model)</u>	0998-00-0800-35
<u>Cardiosave Intra-aortic Balloon Pump (Hybrid model)</u>	0998-00-0800-52
<u>Cardiosave Intra-aortic Balloon Pump (Hybrid model)</u>	0998-00-0800-55
<u>Cardiosave Intra-aortic Balloon Pump (Rescue model)</u>	0998-00-0800-85

Accessories included with the device (Hybrid and Rescue):

Product Description	Product-No.
CARDIOSAVE <u>Accessory</u> Kit, AAMI	0020-00-0480-01
CARDIOSAVE <u>Accessory</u> Kit, IEC	0020-00-0480-02
CARDIOSAVE Li-ion <u>Battery</u> Pack	0146-00-0097
CARDIOSAVE Li-ion <u>Battery Transport</u> and <u>Storage</u> Case	0202-00-0206-01

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Standard Accessories for Cardiosave Rescue only:

Product Description	Product-No.
CARDIOSAVE Helium Refilling Station	0998-00-0801
CARDIOSAVE Battery Charging Station	0998-00-0802
CARDIOSAVE AC Transport Power Supply (Bulk Jr.)	0014-00-0085
CARDIOSAVE Mounting Plate	0436-00-0223

Optional Accessories for Cardiosave (Hybrid and Rescue):

Product Description	Product-No
Helium Tank - Reusable - <u>Single</u> Tank	0075-00-0024-01
Helium Tank - Reusable - Pack of 3 Tanks	0075-00-0024-03
Helium Tank - Reusable - Pack of 3 Tanks - <u>Empty</u>	0075-00-0034-03
Non-Domestic Helium Tank - Reusable - Pack of 3 Tanks - <u>Empty</u>	0075-00-0061-03
Helium Tank - UK/ France - Reusable - Pack of 3 Tanks	0075-02-0001-03
Helium Tank - German - Reusable - Pack of 3 Tanks	0075-02-0002-03
Helium Tank - <u>Disposable</u> - <u>Single</u> Tank - Full	202-00-0104
External <u>Signal</u> Cable	0012-00-0323
30' Cable Interfaces BP and ECG for HP/Philips Monitors, except CMS, Viridia or Intellivue, RoHS	0012-00-0819-03
30' Cable Interfaces ECG for HP/Philips CMS, Viridia, Intellivue and MP series monitors, RoHS	0012-00-0820-03
30' Cable Interfaces BP for Philips Viridia and BP and ECG for <u>Spacelabs</u> PC series monitors, RoHS	0012-00-0822-03
30' Cable Interfaces BP and ECG for GE <u>Marquette</u> monitors, RoHS	0012-00-0825-03
30' Cable Interfaces ECG for Spacelabs PC series monitors with TT-253 <u>plugs</u> , RoHS	0012-00-0826-03

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Product Description	Product-No.
Interface Transducer Cable	0012-00-1245
Low Level <u>Output</u> Cable - Unterminated - 15' (457.2cm)	0012-00-1589-01
Low Level <u>Output</u> Cable - Interface to <u>Datascope</u> Monitor	0012-00-1589-02
Low Level <u>Output</u> Cable - Interface to <u>Philips</u> monitor	0012-00-1589-03
Low Level <u>Output</u> Cable - Interface to GE monitor	0012-00-1589-04
Low Level <u>Output</u> Cable - Unterminated - 23' (701cm)	0012-00-1589-05
ECG Patient Cable - 5 Lead - 10' (304.8cm) - <b>AAMI</b>	0012-00-1812-01
ECG Patient Cable - 5 Lead - 10' (304.8cm) - IEC	0012-00-1812-02
ECG Leadwires - 5 Lead - Pinch <u>Type</u> - 50" (127cm) - <b>AAMI</b>	0012-00-1813-01
ECG Leadwires - 5 Lead - Pinch <u>Type</u> - 50" (127cm) - IEC	0012-00-1813-02
ECG ESIS Leadwires - 5 Lead - Pinch <u>Type</u> - 50" (127cm) - <b>AAMI</b>	0012-00-1814-01
ECG ESIS Leadwires - 5 Lead - Pinch <u>Type</u> - 50" (127cm) - IEC	0012-00-1814-02
<u>Adapter</u> Cable, Blood Pressure Transducer	0012-00-1815
AC Line Cord - NEMA 5-15P ( <u>Type B plug</u> )	0012-00-1823-01
AC Line Cord - CEE 7/7 ( <u>Type E/F plug</u> )	0012-00-1823-02
AC Line Cord - GB2099 ( <u>Type I plug</u> )	0012-00-1823-03
AC Line Cord - BS1363 ( <u>Type G plug</u> )	0012-00-1823-04
AC Line Cord - AS/NZS 3112 ( <u>Type I plug</u> )	0012-00-1823-05
AC Line Cord - SEV 1001 ( <u>Type J plug</u> )	0012-00-1823-06
AC Line Cord - SABS 164-1 ( <u>Type M plug</u> )	0012-00-1823-07
AC Line Cord - IA6A3 ( <u>Type D plug</u> )	0012-00-1823-08
AC Line Cord - DK-2-8A ( <u>Type K plug</u> )	0012-00-1823-09
Plastic Weather Cover	0198-00-0087