ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 104155 0006 Rev. 00

Manufacturer: **Datascope Corp**
15 Law Drive
Fairfield NJ 07004
USA

Product: **Catheters for Single Use**
Intra-Aortic Balloon Catheters and Kits

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:G7 104155 0006 Rev. 00

Report no.: 713174753

Valid from: 2020-08-17
Valid until: 2024-05-26

Date, 2020-08-17

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 104155 0006 Rev. 00

Model(s): **Intra-Aortic Balloon Catheters and Kits**

Parameter:

Device Name	Part No.
LINEAR 7.5 Fr 25cc Intra-aortic Balloon Catheter	0684-00-0478-01, 0684-00-0478-02, 0684-00-0478-07, 0684-00-0478-08, 0684-00-0478-09, 0684-00-0478-10
LINEAR 7.5Fr 34cc Intra-Aortic Balloon Catheter	0684-00-0479-01, 0684-00-0479-02, 0684-00-0479-07, 0684-00-0479-08, 0684-00-0479-09,0684-00-0479-10
LINEAR 7.5Fr 40cc Intra-Aortic Balloon Catheter	0684-00-0480-01, 0684-00-0480-02, 0684-00-0480-07, 0684-00-0480-08, 0684-00-0480-09, 0684-00-0480-10
MEGA 7.5Fr 30cc Intra-Aortic Balloon Catheter	0684-00-0294-01, 0684-00-0294-02, 0684-00-0294-03, 0684-00-0294-05, 0684-00-0294-07, 0684-00-0294-08, 0684-00-0294-09, 0684-00-0294-10
MEGA 7.5Fr 40cc Intra-Aortic Balloon Catheter	0684-00-0295-01, 0684-00-0295-02,0684-00-0295-03, 0684-00-0295-05, 0684-00-0295-07, 0684-00-0295-08, 0684-00-0295-09, 0684-00-0295-10
MEGA 8Fr 50cc Intra-Aortic Balloon Catheter	0684-00-0498-01, 0684-00-0498-07,0684-00-0498-08,0684-00-0296-01, 0684-00-0296-02, 0684-00-0296-03, 0684-00-0296-09,0684-00-0296-10
SENSATION 7Fr 34cc Intra-Aortic Balloon Catheter	0684-00-0469-01, 0684-00-0469-07, 0684-00-0469-09
SENSATION 7Fr 40cc Intra-Aortic Balloon Catheter	0684-00-0470-01, 0684-00-0470-07, 0684-00-0470-09
SENSATION PLUS 7.5Fr 40cc Intra-Aortic Balloon Catheter	0684-00-0568-01, 0684-00-0568-03, 0684-00-0568-09
SENSATION PLUS 8Fr 50cc Intra-Aortic Balloon Catheter	0684-00-0576-01, 0684-00-0576-03, 0684-00-0576-09

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

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 104155 0006 Rev. 00

Accessories included with the device

Device Name	Part No.
LINEAR 25cc Insertion Kit*	0684-00-0477
LINEAR 34cc & 40cc Insertion Kit*	0684-00-0476
MEGA 30cc & 40cc Insertion Kit*	0684-00-0291
MEGA 50cc Insertion Kit*	0684-00-0496
SENSATION 34cc & 40cc Insertion Kit*	0684-00-0467
SENSATION PLUS 40cc Insertion Kit*	0684-00-0566
SENSATION PLUS 50cc Insertion Kit*	0684-00-0574

Further Accessories

Packaged Insertion Kit	Part No.
Linear 7.5Fr 25cc IAB	0884-00-0019-12
Linear 7.5Fr 34 & 40cc IABs	0884-00-0019-13
Sensation 7Fr 34 & 40cc IABs	0884-00-0019-16
Mega 8Fr 50cc IAB	0884-00-0019-17
Mega 7.5Fr 30 & 40cc IABs	0884-00-0019-21
Sensation Plus 7.5Fr 40cc IAB	0884-00-0019-22
Sensation Plus 8Fr 50cc IAB	0884-00-0019-23

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

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EB sertifikatas

EB projekto tyrimo sertifikatas
Direktyvos 93/42/EEB dėl medicinos prietaisų (MDD) II priedo 4 dalis
(III klasės prietaisai)

Nr. G7 104155 0006 Perž. 00

Gamintojas: **„Datascope Corp“**
15 Law Drive
Fairfield NJ 07004
JAV

Produktas: **Vienkartinio naudojimo intraaortiniai balioniniai kateteriai ir jų rinkiniai**

„TÜV SÜD Product Service GmbH“ sertifikavimo įstaiga patvirtina, kad buvo atliktas atitinkamų prietaisų projekto tyrimas pagal MDD II priedo 4 dalį. Prietaisų projektas atitinka šios direktyvos reikalavimus. Norint prekiauti šiais prietaisais, privaloma pateikti papildomą II priedo sertifikatą. Turi būti laikomasi visų taikytinų „TÜV SÜD“ grupės bandymų ir sertifikavimo nuostatų reikalavimų. Išsamią informaciją ir sertifikato galiojimo duomenis rasite čia: www.tuvsud.com/ps-cert?q=cert:G7 104155 0006 Rev. 00

Ataskaitos Nr.: 713174753

Galioja nuo: 2020-08-17
Galioja iki: 2024-05-26

Data: 2020-08-17

Sertifikavimo/notifikuotosios įstaigos vadovas

„TÜV SÜD Product Service GmbH“ yra notifikuotoji įstaiga su identifikaciniu Nr. 0123

EB sertifikatas

EB projekto tyrimo sertifikatas
Direktyvos 93/42/EEB dėl medicinos prietaisų (MDD) II priedo 4 dalis
(III klasės prietaisai)

Nr. G7 104155 0006 Peržiūra 00

Modelis (-iai): **Intraaortiniai balioniniai kateteriai ir jų rinkiniai**

Parametrai:

Prietaiso pavadinimas	Dalies Nr.
LINEAR 7.5 Fr 25cc Intraaortinis balioninis kateteris	0684-00-0478-01, 0684-00-0478-02, 0684-00-0478-07, 0684-00-0478-08, 0684-00-0478-09, 0684-00-0478-10
LINEAR 7.5Fr 34cc Intraaortinis balioninis kateteris	0684-00-0479-01, 0684-00-0479-02, 0684-00-0479-07, 0684-00-0479-08, 0684-00-0479-09,0684-00-0479-10
LINEAR 7.5Fr 40cc Intraaortinis balioninis kateteris	0684-00-0480-01, 0684-00-0480-02, 0684-00-0480-07, 0684-00-0480-08, 0684-00-0480-09, 0684-00-0480-10
MEGA 7.5Fr 30cc Intraaortinis balioninis kateteris	0684-00-0294-01, 0684-00-0294-02, 0684-00-0294-03, 0684-00-0294-05, 0684-00-0294-07, 0684-00-0294-08, 0684-00-0294-09, 0684-00-0294-10
MEGA 7.5Fr 40cc Intraaortinis balioninis kateteris	0684-00-0295-01, 0684-00-0295-02,0684-00-0295-03, 0684-00-0295-05, 0684-00-0295-07, 0684-00-0295-08, 0684-00-0295-09, 0684-00-0295-10
MEGA 8Fr 50cc Intraaortinis balioninis kateteris	0684-00-0498-01, 0684-00-0498-07,0684-00-0498-08,0684-00-0296-01, 0684-00-0296-02, 0684-00-0296-03, 0684-00-0296-09,0684-00-0296-10
SENSATION 7Fr 34cc Intraaortinis balioninis kateteris	0684-00-0469-01, 0684-00-0469-07, 0684-00-0469-09
SENSATION 7Fr 40cc Intraaortinis balioninis kateteris	0684-00-0470-01, 0684-00-0470-07, 0684-00-0470-09
SENSATION PLUS 7.5Fr 40cc Intraaortinis balioninis kateteris	0684-00-0568-01, 0684-00-0568-03, 0684-00-0568-09
SENSATION PLUS 8Fr 50cc Intraaortinis balioninis kateteris	0684-00-0576-01, 0684-00-0576-03, 0684-00-0576-09

„TÜV SÜD Product Service GmbH“ yra notifikuotoji įstaiga su identifikaciniu Nr. 0123
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EB sertifikatas

EB projekto tyrimo sertifikatas
Direktyvos 93/42/EEB dėl medicinos prietaisų (MDD) II priedo 4 dalis (III klasės prietaisai)

Nr. G7 104155 0006 Perž. 00

Kartu su prietaisu tiekiami priedai

Prietaiso pavadinimas	Dalies Nr.
LINEAR 25cc Įvedimo rinkinys*	0684-00-0477
LINEAR 34cc & 40cc Įvedimo rinkinys*	0684-00-0476
MEGA 30cc & 40cc Įvedimo rinkinys *	0684-00-0291
MEGA 50cc Įvedimo rinkinys *	0684-00-0496
SENSATION 34cc & 40cc Įvedimo rinkinys*	0684-00-0467
SENSATION PLUS 40cc Įvedimo rinkinys *	0684-00-0566
SENSATION PLUS 50cc Įvedimo rinkinys *	0684-00-0574

Kiti priedai

Įvedimo rinkinys pakuotėje	Dalies Nr.
Linear 7.5Fr 25cc IAB	0884-00-0019-12
Linear 7.5Fr 34 & 40cc IABs	0884-00-0019-13
Sensation 7Fr 34 & 40cc IABs	0884-00-0019-16
Mega 8Fr 50cc IAB	0884-00-0019-17
Mega 7.5Fr 30 & 40cc IABs	0884-00-0019-21
Sensation Plus 7.5Fr 40cc IAB	0884-00-0019-22
Sensation Plus 8Fr 50cc IAB	0884-00-0019-23

„TÜV SÜD Product Service GmbH“ yra notifikuotoji įstaiga su identifikaciniu Nr. 0123

GETINGE

EC DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

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

Name and Address of the Manufacturer:	Datascope Corp. 15 Law Drive, Fairfield, NJ 07004 USA
Name and Address of the Authorised Representative:	MAQUET Critical Care Röntgenvägen 2 171 06 Solna Sweden

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

Product Description:	Intra-Aortic Balloon Catheter and its accessories
Product-No.:	Refer to Appendix A of this document
Classification (acc. to Annex IX of MDD):	Class III, Rule 7, Invasive Device

Product Description:	Insertion Kits
Product-No.:	Refer to Appendix A of this document
Classification (acc. to Annex IX of MDD):	Class III, Rule 7, Invasive Device

Product Description:	Guidewires
Product-No.:	Refer to Appendix A of this document
Classification (acc. to Annex IX of MDD):	Class III, Rule 6, Invasive Device

GETINGE

EC DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

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

Product Description:	Introducer Sets (Sheath/Dilators)
Product-No.:	Refer to Appendix A of this document
Classification (acc. to Annex IX of MDD):	Class IIa, Rule 7, Invasive Device
Product Description:	Catheter Extenders, Arrow Pump Adapters
Product-No.:	Refer to Appendix A of this document
Classification (acc. to Annex IX of MDD):	Class IIa, Rule 2, Non-Invasive Device

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

Directive 93/42/EEC on Medical Devices

Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Germany CE 0123
Conformity Assessment Procedure:	Class III, acc. to Annex II including 4 of Directive 93/42/EEC Class IIa, acc. to Annex II.3 excluding 4 of Directive 93/42/EEC

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

[redacted] Director of Regulatory Affairs
Signed on behalf of Datascope Corp.

Datascope Corp.
15 Law Drive
Fairfield, NJ 07004
USA

GETINGE

EC DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

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

Appendix A

Intra-aortic Balloon Catheters

Product Name	Model Number
Linear 7.5Fr. IAB	**25cc:** 0684-00-0478-01, 0684-00-0478-02, 0684-00-0478-07, 0684-00-0478-08, 0684-00-0478-09, 0684-00-0478-10 **34cc:** 0684-00-0479-01, 0684-00-0479-02, 0684-00-0479-07, 0684-00-0479-08, 0684-00-0479-09, 0684-00-0479-10 **40cc:** 0684-00-0480-01, 0684-00-0480-02, 0684-00-0480-07, 0684-00-0480-08, 0684-00-0480-09, 0684-00-0480-10
Mega 8Fr. IAB	**50cc:** 0684-00-0498-01, 0684-00-0498-07, 0684-00-0498-08, 0684-00-0296-01, 0684-00-0296-02, 0684-00-0296-03, 0684-00-0296-09, 0684-00-0296-10
Mega 7.5Fr. IAB	**30cc:** 0684-00-0294-01, 0684-00-0294-02, 0684-00-0294-03, 0684-00-0294-05, 0684-00-0294-07, 0684-00-0294-08, 0684-00-0294-09, 0684-00-0294-10 **40cc**: 0684-00-0295-01, 0684-00-0295-02, 0684-00-0295-03, 0684-00-0295-05, 0684-00-0295-07, 0684-00-0295-08, 0684-00-0295-09, 0684-00-0295-10
Sensation 7Fr. IAB	**34cc:** 0684-00-0469-01, 0684-00-0469-07, 0684-00-0469-09 **40cc:** 0684-00-0470-01, 0684-00-0470-07, 0684-00-0470-09
Sensation Plus 8Fr. IAB	**50cc:** 0684-00-0576-01, 0684-00-0576-03, 0684-00-0576-09
Sensation Plus 7.5Fr IAB	**40cc:** 0684-00-0568-01, 0684-00-0568-03, 0684-00-0568-09

Datascope Corp.
15 Law Drive
Fairfield, NJ 07004
USA

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EC DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

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

Insertion Kits

Product Name	Model Number
Linear 7.5Fr 25cc	0884-00-0019-12
Linear 7.5Fr 40cc & 34cc	0884-00-0019-13
Mega 7.5Fr 30cc/40cc	0884-00-0019-21
Mega 8Fr 50cc	0884-00-0019-17
Sensation 7Fr 40cc & 34cc	0884-00-0019-16
Sensation Plus 7.5Fr 40cc	0884-00-0019-22
Sensation Plus 8Fr 50cc	0884-00-0019-23

Introducer Sets (Sheath/Dilator)

Product Name	Model Number
Reinforced Introducer Set for use with 7Fr IAB Catheters	0684-00-0403-06
Reinforced Introducer Set for use with 7.5Fr IAB Catheters	0684-00-0403-05
Reinforced Introducer Set for use with 8Fr IAB Catheters	0684-00-0403-10

Catheter Extenders

Product Name	Model Number
Catheter Extender for 40cc & 34cc IABs (Sensation & Linear)	0684-00-0186
Catheter Extender for 50cc IABs (Sensation Plus 8Fr & Mega 8Fr)	0684-00-0526
Catheter Extender for 30cc & 40cc IABs (Mega 7.5Fr)	0684-00-0275
Catheter Extender for 25cc IABs (Linear)	0684-00-0335

Arrow Pump Adapters

Product Name	Model Number
Arrow Pump Adapter for 25cc to 40cc IABs	0684-00-0510-01

Datascope Corp.
15 Law Drive
Fairfield, NJ 07004
USA

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EC DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

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

Arrow Pump Adapter for 50cc IABs	0684-00-0510-02

Guidewires

Product Name	Model Number
Guidewires for 7.5 Fr or 8 Fr. IAB catheters	
0.025" X 145cm 3mm J PTFE Stainless Steel Guidewire (Box of 5)	0684-00-0254-09
0.025" X 175cm 3mm J PTFE Stainless Steel Guidewire (Box of 5)	0684-00-0254-14
0.025" X 260cm 3mm J PTFE Stainless Steel Guidewire (Box of 5)	0684-00-0254-15
Guidewires for 7 Fr. IAB catheters	
0.018" x 145cm 3mm J PTFE Stainless Steel Guidewire (Box of 5)	0684-00-0254-16
0.035" x 55cm 3mm J Stainless Steel Uncoated Introducer Guidewire (Box of 5)	0684-00-0254-17

Datascope Corp.
15 Law Drive
Fairfield, NJ 07004
USA

Add value.
Inspire trust.

TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

Datascope Corp
15 Law Drive
07004 FAIRFIELD
USA

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
104155	713225723, 713266341, 713204729, 713214059	+49 89 54911-677 rebeccagrazek@tuvsud.com	NA	2024-02-28	1 of 8

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 104155 0012 Rev. 01

Reference: 713225723, 713266341, 713204729, 713214059

To whom it may concern,

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

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: US-MF-000015588

The devices covered by the formal application and the written agreement mentioned above are identified in the Table below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or

- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

The issuance of the first confirmation letter is free of charge. We reserve the right to invoice further copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL 104155 0012 Rev. 01

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-02-28

TÜV SÜD Product Service GmbH
Medical and Health Services
2024-01-11

Conformity Assessment Responsible (CARE)
Acting Project Handler (APH)

TÜV SÜD Product Service GmbH
Medical and Health Services

Application Reviewer

TÜV SÜD Product Service GmbH
Medical and Health Services

Project Handler (PH)

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Article Number (Product Code)	Device name or Basic UDI-DI (under MDR application)	MDR Class	MDD Class	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification; MDD 93/42/EEC Annex II.3
Device 1: **0684-00-0498-01**	MEGA IAB Catheters 8Fr 50cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 2: **0684-00-0498-07**	MEGA IAB Catheters 8Fr 50cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 3: **0684-00-0498-08**	MEGA IAB Catheters 8Fr 50cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 4: **0684-00-0296-01**	MEGA IAB Catheters 8Fr 50cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 5: **0684-00-0296-02**	MEGA IAB Catheters 8Fr 50cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 6: **0684-00-0296-03**	MEGA IAB Catheters 8Fr 50cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 7: **0684-00-0296-09**	MEGA IAB Catheters 8Fr 50cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 8: **0684-00-0296-10**	MEGA IAB Catheters 8Fr 50cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 9: **0684-00-0295-01**	MEGA IAB Catheters 7.5Fr 40cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 10: **0684-00-0295-02**	MEGA IAB Catheters 7.5Fr 40cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 11:	MEGA IAB Catheters 7.5Fr 40cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123

Article Number (Product Code)	Device name or Basic UDI-DI (under MDR application)	MDR Class	MDD Class	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification; MDD 93/42/EEC Annex II.3
0684-00-0295-03					
Device 12: **0684-00-0295-05**	MEGA IAB Catheters 7.5Fr 40cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 13: **0684-00-0295-07**	MEGA IAB Catheters 7.5Fr 40cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 14: **0684-00-0295-08**	MEGA IAB Catheters 7.5Fr 40cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 15: **0684-00-0295-09**	MEGA IAB Catheters 7.5Fr 40cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 16: **0684-00-0295-10**	MEGA IAB Catheters 7.5Fr 40cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 17: **0684-00-0294-01**	MEGA IAB Catheters 7.5Fr 30cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 18: **0684-00-0294-02**	MEGA IAB Catheters 7.5Fr 30cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 19: **0684-00-0294-03**	MEGA IAB Catheters 7.5Fr 30cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 20: **0684-00-0294-05**	MEGA IAB Catheters 7.5Fr 30cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 21: **0684-00-0294-07**	MEGA IAB Catheters 7.5Fr 30cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 22:	MEGA IAB Catheters 7.5Fr 30cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123

Article Number (Product Code)	Device name or Basic UDI-DI (under MDR application)	MDR Class	MDD Class	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification; MDD 93/42/EEC Annex II.3
0684-00-0294-08					
Device 23: **0684-00-0294-09**	MEGA IAB Catheters 7.5Fr 30cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 24: **0684-00-0294-10**	MEGA IAB Catheters 7.5Fr 30cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 25: **0884-00-0019-17**	Mega 8Fr 50cc Insertion Kit 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 26: **0884-00-0019-21**	Mega 7.5Fr 30cc/40cc Insertion Kit 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 27: **0684-00-0576-01**	Sensation Plus 8Fr 50cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 28: **0684-00-0576-03**	Sensation Plus 8Fr 50cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 29: **0684-00-0576-09**	Sensation Plus 8Fr 50cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 30: **0684-00-0568-01**	Sensation Plus 7.5Fr 40cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 31: **0684-00-0568-03**	Sensation Plus 7.5Fr 40cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 32: **0684-00-0568-09**	Sensation Plus 7.5Fr 40cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 33: **0684-00-0469-01**	Sensation 7Fr 34cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123

Article Number (Product Code)	Device name or Basic UDI-DI (under MDR application)	MDR Class	MDD Class	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification; MDD 93/42/EEC Annex II.3
Device 34: **0684-00-0469-07**	Sensation 7Fr 34cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 35: **0684-00-0469-09**	Sensation 7Fr 34cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 36: **0684-00-0470-01**	Sensation 7Fr 40cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 37: **0684-00-0470-07**	Sensation 7Fr 40cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 38: **0684-00-0470-09**	Sensation 7Fr 40cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 39: **0684-00-0478-01**	Linear 7.5Fr 25cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 40: **0684-00-0478-02**	Linear 7.5Fr 25cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 41: **0684-00-0478-07**	Linear 7.5Fr 25cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 42: **0684-00-0478-08**	Linear 7.5Fr 25cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 43: **0684-00-0478-09**	Linear 7.5Fr 25cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 44: **0684-00-0478-10**	Linear 7.5Fr 25cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 45:	Linear 7.5Fr 34cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123

Article Number (Product Code)	Device name or Basic UDI-DI (under MDR application)	MDR Class	MDD Class	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification; MDD 93/42/EEC Annex II.3
0684-00-0479-01					
Device 46: **0684-00-0479-02**	Linear 7.5Fr 34cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 47: **0684-00-0479-07**	Linear 7.5Fr 34cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 48: **0684-00-0479-08**	Linear 7.5Fr 34cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 49: **0684-00-0479-09**	Linear 7.5Fr 34cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 50: **0684-00-0479-10**	Linear 7.5Fr 34cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 51: **0684-00-0480-01**	Linear 7.5Fr 40cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 52: **0684-00-0480-02**	Linear 7.5Fr 40cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 53: **0684-00-0480-07**	Linear 7.5Fr 40cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 54: **0684-00-0480-08**	Linear 7.5Fr 40cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 55: **0684-00-0480-09**	Linear 7.5Fr 40cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 56:	Linear 7.5Fr 40cc 06075670684IABCRH	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123

Article Number (Product Code)	Device name or Basic UDI-DI (under MDR application)	MDR Class	MDD Class	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification; MDD 93/42/EEC Annex II.3
0684-00-0480-10					
Device 57: **0884-00-00193-23**	Sensation Plus 8Fr 50cc Insertion Kit 06075670884IK49	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123
Device 58: **0884-00-00193-22**	Sensation Plus 7.5Fr 40cc Insertion Kit 06075670884IK49	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123
Device 59: **0884-00-0019-16**	Sensation 7Fr 40cc & 34cc Insertion Kit 06075670884IK49	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 60: **0884-00-0019-13**	Linear 7.5Fr 40cc & 34cc Insertion Kit 06075670884IK49	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123
Device 61: **0884-00-0019-12**	Linear 7.5Fr 25cc Insertion Kit 06075670884IK49	III	III	N/A	Certification as follows: G1 104155 0005 Rev. 00; NB0123 G7 104155 0006 rev 00; NB0123

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-02-16	713225723 / 713266341 / 713204729 / 713214059	Initial issue
2024-02-28		Device 0884-00-00193-23 and 0884-00-00193-22 added

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„Datascope Corp“
15 Law Drive
07004 FAIRFIELD
JAV

Jūsų nuoroda (raštas)	Mūsų nuoroda (pavadinimas)	Tel. numeris, el. paštas	Fakso numeris	Data	Puslapis
104155	713225723, 713266341, 713204729, 713214059	+49 89 54911-677 rebeccagrazek@tuvsud.com	NA	2024-02-28	1 iš 8

„TÜV SÜD Product Service“ GmbH
Patvirtinimo raštas
CL 104155 0012 Rev. 01

Nuoroda: 713225723, 713266341, 713204729, 713214059

Visiems suinteresuotiesiems

Oficialios paraiškos, rašytinio susitarimo ir tinkamos priežiūros statuso patvirtinimas pagal Reglamentą (ES) 2023/607, kuriuo dėl tam tikroms medicinos priemonėms ir *in vitro* diagnostikos medicinos priemonėms taikomų pereinamojo laikotarpio nuostatų iš dalies keičiami reglamentai (ES) 2017/745 (toliau – medicinos priemonių reglamentas arba MDR).

Šiuo raštu „TÜV SÜD Product Service“ GmbH, pagal MDR paskirta bendrovė, NANDO sistemoje pažymėta numeriu 0123, patvirtina, kad gavo oficialią paraišką pagal MDR VII priedo 4.3 skirsnio pirmą pastraipą ir pasirašė rašytinį susitarimą pagal MDR VII priedo 4.3 skirsnio antrą pastraipą su pirmiau nurodytu gamintoju, kuriam suteiktas šis SRN numeris:

SRN numeris: US-MF-000015588

Prietaisai, dėl kurių pateikta pirmiau minėta oficiali paraiška ir rašytinis susitarimas, nurodyti toliau pateiktoje lentelėje.

- 1 lentelėje nurodyti prietaisai, dėl kurių gauta MDR paraiška, sudarytas rašytinis susitarimas ir kurių atžvilgiu „TÜV SÜD Product Service“ GmbH privalo vykdyti deramą atitinkamų prietaisų priežiūrą pagal galiojančią direktyvą.

Jei prietaisams taikomi sertifikatai, išduoti pagal Direktyvą 90/385/EEB (AIMDD) arba Direktyvą 93/42/EEB (MDD), kurių galiojimas baigėsi nuo 2021 m. gegužės 26 d. iki 2023 m. kovo 20 d., bet jie nebuvo išimti iš apyvartos, šiuo raštu taip pat patvirtinama, kad

- gamintojas rašytinį susitarimą pagal MDR pasirašė iki MDD/AIMDD sertifikato galiojimo pabaigos dienos;

- arba pateikė įrodymų, kad valstybės narės kompetentinga institucija pagal MDR 59 straipsnio 1 dalį arba MDR 97 straipsnio 1 dalį atitinkamai leido nukrypti nuo galiojančios atitikties įvertinimo tvarkos arba jai taikyti išimtį.

Toliau nurodyti pereinamojo laikotarpio terminai pagal MDR 120 straipsnio 3 dalį, kurie galioja šiame rašte nurodytiems prietaisams, jei gamintojas ir toliau laikosi kitų MDR 120 straipsnio 3c dalyje nurodytų sąlygų:

- 2026 m. gegužės 26 d. III klasės pagal užsakymą pagamintiems implantuojamiems prietaisams;
- 2027 m. gruodžio 31 d. III klasės prietaisams ir IIb klasės implantuojamiems prietaisams (išskyrus siūlus žaizdai susiūti, kabes, dantų plombas, dantų breketus, dantų vainikėlius, varžtus, pleištus, plokšteles, vielas, vinis, apkabėles ir jungtis);
- 2028 m. gruodžio 31 d. kitiems IIb klasės, IIa klasės, I klasės prietaisams, kurie rinkai tiekiami sterilūs ir turi matavimo funkciją;
- 2028 m. gruodžio 31 d. prietaisams, kurių atžvilgiu notifikuotoji įstaiga neprivalo dalyvauti pagal MDD, bet privalo dalyvauti pagal MDR (pvz., I klasės prietaisams, kurie laikomi daugkartinio naudojimo chirurginiais instrumentais).

Pirmasis patvirtinimo raštas išduodamas nemokamai. Pagal pastangas pasiliekame teisę išrašyti sąskaitą už tolesnes patvirtinimo rašto kopijas, jo papildymus ir (arba) pakeitimus.

Dėl patvirtinimo rašto galiojimo žr. www.tuvsud.com/ps-cert?q=cert:CL 104155 0012 Rev. 01

Jei turite klausimų, kreipkitės į medical_devices@tuvsud.com.

Notifikuotosios įstaigos, „TÜV SÜD Product Service“ GmbH, vardu
2024-02-28

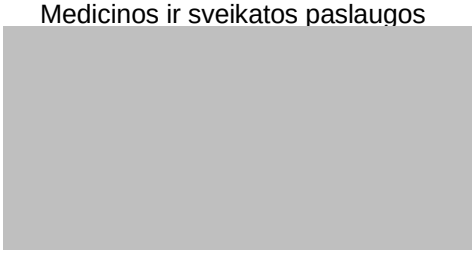
„TÜV SÜD Product Service“ GmbH
Medicinos ir sveikatos paslaugos
2024-01-11

Atsakinga už atitikties vertinimą (CARE)
L. e. projekto vadovo pareigas (APH)

„TÜV SÜD Product Service“ GmbH
Medicinos ir sveikatos paslaugos

Paraiškų vertintoja

„TÜV SÜD Product Service“ GmbH
Medicinos ir sveikatos paslaugos



Projekto vadovė (PH)