




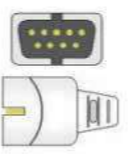






Original Product Information			Caredem Product Information					
Original Brand	Original P/N	Monitor end plug	Caredem P/N Cotton stretch fabric	Caredem P/N Foam Adhesive	Caredem P/N Non-Adhesive	Description	Price	Adaptor cable
<b>Nihon Kohden</b>	TL-271T		SA09T-16	SA09F-16	SN09N-16	Adult(>40kg) , 0.9m	B2	Standard cables See Spo2 reusable section
	TL-272T		SP09T-16	SP09F-16	SI09N-16	Pediatric(10-50kg), 0.9m	B2	
	TL-274T		SI09T-16	SI09F-16	SI09N-16	Infant(3-20kg), 0.9m	B2	
	TL-273T		SN09T-16	SN09F-16	SN09N-16	Neonate(<3kg), 0.9m	B2	
<b>BCI</b>	1300		SA09T-06	SA09F-06	SN09N-06	Adult(>40kg) , 0.9m	B1	Standard cables See Spo2 reusable section
	1301		SP09T-06	SP09F-06	SI09N-06	Pediatric(10-50kg), 0.9m	B1	
	1303		SI09T-06	SI09F-06	SI09N-06	Infant(3-20kg), 0.9m	B1	
	1302		SN09T-06	SN09F-06	SN09N-06	Neonate(<3kg), 0.9m	B1	
<b>Biolight Digital -Tech</b>	—		SA09T-62D	SA09F-62D	SN09N-62D	Adult(>40kg) , 0.9m	B1	Standard cables See Spo2 reusable section
			SP09T-62D	SP09F-62D	SI09N-62D	Pediatric(10-50kg), 0.9m	B1	
			SI09T-62D	SI09F-62D	SI09N-62D	Infant(3-20kg), 0.9m	B1	
			SN09T-62D	SN09F-62D	SN09N-62D	Neonate(<3kg), 0.9m	B1	
<b>Datex</b>	SAS-AF		SA09T-09	SA09F-09	SN09N-09	Adult(>40kg) , 0.9m	B1	Standard cables See Spo2 reusable section
	SAS-AP		SP09T-09	SP09F-09	SI09N-09	Pediatric(10-50kg), 0.9m	B1	
	SAS-AP		SI09T-09	SI09F-09	SI09N-09	Infant(3-20kg), 0.9m	B1	
	SAS-AF		SN09T-09	SN09F-09	SN09N-09	Neonate(<3kg), 0.9m	B1	
<b>Datascope</b>	0998-00-0076-05		SA09T-07	SA09F-07	SN09N-07	Adult(>40kg) , 0.9m	B2	Standard cables See Spo2 reusable section
	0998-00-0076-04		SP09T-07	SP09F-07	SI09N-07	Pediatric(10-50kg), 0.9m	B2	
	0998-00-0074-03		SI09T-07	SI09F-07	SI09N-07	Infant(3-20kg), 0.9m	B2	
	0998-00-0074-04		SN09T-07	SN09F-07	SN09N-07	Neonate(<3kg), 0.9m	B2	

Original Product Information			Caredem Product Information					
Original Brand	Original P/N	Monitor end plug	Caredem P/N Cotton stretch fabric	Caredem P/N Foam Adhesive	Caredem P/N Non-Adhesive	Description	Price	Adaptor cable
<b>Digital -Tech</b>	—		SA09T-42D	SA09F-42D	SN09N-42D	Adult(>40kg) , 0.9m	B2	Standard cables See Spo2 reusable section
			SP09T-42D	SP09F-42D	SI09N-42D	Pediatric(10-50kg), 0.9m	B2	
			SI09T-42D	SI09F-42D	SI09N-42D	Infant(3-20kg), 0.9m	B2	
			SN09T-42D	SN09F-42D	SN09N-42D	Neonate(<3kg), 0.9m	B2	
<b>Dixtal</b>	—		SA09T-113	SA09F-113	SN09N-113	Adult(>40kg) , 0.9m	B2	Standard cables See Spo2 reusable section
			SP09T-113	SP09F-113	SI09N-113	Pediatric(10-50kg), 0.9m	B2	
			SI09T-113	SI09F-113	SI09N-113	Infant(3-20kg), 0.9m	B2	
			SN09T-113	SN09F-113	SN09N-113	Neonate(<3kg), 0.9m	B2	
<b>Nova -metrix</b>	AS110		SA09T-03	SA09F-03	SN09N-03	Adult(>40kg) , 0.9m	B2	SZ22-03 cable is required
	AS120		SP09T-03	SP09F-03	SI09N-03	Pediatric(10-50kg), 0.9m	B2	
	AS130		SI09T-03	SI09F-03	SI09N-03	Infant(3-20kg), 0.9m	B2	
	AS140		SN09T-03	SN09F-03	SN09N-03	Neonate(<3kg), 0.9m	B2	
<b>MEK</b>	—		SA09T-26	SA09F-26	SN09N-26	Adult(>40kg) , 0.9m	B2	SZ22-03 cable is required
			SP09T-26	SP09F-26	SI09N-26	Pediatric(10-50kg), 0.9m	B2	
			SI09T-26	SI09F-26	SI09N-26	Infant(3-20kg), 0.9m	B2	
			SN09T-26	SN09F-26	SN09N-26	Neonate(<3kg), 0.9m	B2	
<b>*M-Tech</b>	2317/LNCS Amtx-3		SA09T-49	SA09F-49	SN09N-49	Adult(>40kg) , 0.9m	B2	—
	2318/LNCS Pmtx-3		SP09T-49	SP09F-49	SI09N-49	Pediatric(10-50kg), 0.9m	B2	
	2319/LNCS Inf-3		SI09T-49	SI09F-49	SI09N-49	Infant(3-20kg), 0.9m	B2	
	2320/LNCS Neo-3		SN09T-49	SN09F-49	SN09N-49	Neonate(<3kg), 0.9m	B2	

Original Product Information				Caremed Product Information							
Original Brand	Original Model	Original P/N	Monitor side	Caremed P/N	Cable Length	Description	Price (unit)	Adaptor cable			
								Monitor side	Sensor side		
Philips/HP	78352C, 78354C, 78834C, M1020A, M1025B, M1025A, M1350B, M1772A/B, M1732A/B, M2475B (*Non-Oximax)	DS100A		SA11Y-01	1.1M	Adult, Fish clip	C3				
		DS100A		SA11S-01	1.1M	Adult, Soft finger	C5				
		D-YS		SA11M-01	1.1M	Adult, Multi-purpose	C3				
		M1196A		SA11Y-91	1.1M	Adult, Fish clip	C8				
		-		SA30Y-91	3.0M	Adult, Soft finger	C8				
		M1192A		SP11Y-91	1.1M	Adult, Fish clip	D1				
		M1191A		SA11S-91	1.1M	Pediatrics, Fish clip	D1				
		-		SA30S-91	3.0M	Adult, Soft finger	D1				
		M1192A		SP11S-91	1.1M	Pediatrics, Soft finger	D1				
		M1195A		SI11S-91	1.1M	Infant, Soft finger	D1				
		M1193A		SN11W-91	1.1M	Neonate, Wrap	D1				
		-		SA11M-91	1.1M	Adult, Multi-purpose	D1				
		-		SA11E-91	1.1M	Adult, Ear clip	D1				
		-		SA11F-91	1.1M	Adult, Forehead	D1				
		M1190A		SA30Y-20	3.0M	Adult, Fish clip	C8	NO	NO		
		-		SP30Y-20	3.0M	Pediatrics, Fish clip	D1	NO	NO		
		M1190A		SA30S-20	3.0M	Adult, Soft finger	D1	NO	NO		
		-		SP30S-20	3.0M	Pediatrics, Soft finger	D1	NO	NO		
		-		SI30S-20	3.0M	Infant, Soft finger	D1	NO	NO		
		-		SN30W-20	3.0M	Neonate, Wrap	D1	NO	NO		
		-		SA30M-20	3.0M	Adult, Multi-purpose	C8	NO	NO		
		-		SA30E-20	3.0M	Adult, Ear clip	D1	NO	NO		
		C1,C3,M3,M4, VirDia, MP20,MP30, MP40/50/60/70/90. VM4,VM6,VM8 (Philips*)	See Philips sensor		See Philips sensor						
					See Nellcor Non-Oximax 1.1m						
		A1, A3 (*Non-Oximax)				See Nellcor Non-Oximax 1.1m/3.0m					
		MP20/30/40/50 PM60/70/90 VN4,VM6,VM8 (*Oximax)	DS100A		SA11Y-01X	1.1M	Adult, Fish clip	C5			
			DS100A		SA11S-01X	1.1M	Adult, Soft finger	C7			
			D-YS		SA11M-01X	1.1M	Adult, Multi-purpose	C5			

Original Product Information				Caremed Product Information						
Original Brand	Original Model	Original P/N	Monitor side	Caremed P/N	Cable Length	Description	Price (unit)	Adaptor cable		
								Monitor side	Sensor side	
Philips/HP	Merlin V24 (*M Tech)	1863/ LNCS DCI		SA11Y-49*	1.1M	Adult, Fish clip	C4			
		1863/ LNCS DCI		SA11S-49*	1.1M	Adult, Soft finger	C6			
		2258/ LNCS YI		SA11M-49*	1.1M	Adult, Multi-purpose	C4			
	Merlin V24 (*M Tech)	-		SA30Y-20M	3.0M	Adult, Fish clip	D1	NO	NO	
		-		SA30S-20M	3.0M	Adult, Soft finger	D2	NO	NO	
		-		SA30M-20M	3.0M	Adult, Multi-purpose	D1	NO	NO	
	MP20/30/40/ PM50/60/70/90 VN4,VM6,VM8 (*M tech)	See M 1.1m		See M 1.1m						
		-		SA30Y-91M*	3.0M	Adult, Fish clip	D1	NO	NO	
		-		SA30S-91M*	3.0M	Adult, Soft finger	D2	NO	NO	
	-		SA30M-91M*	3.0M	Adult, Multi-purpose	D1	NO	NO		
	RGB medical	(*BCI)	3044		SA11Y-06	1.1M	Adult, Fish clip	C3		
			-		SA11S-06	1.1M	Adult, Soft finger	C3		
3078				SA11M-06	1.1M	Adult, Multi-purpose	C5			
Schiller ODM/ Bruker	CM8 SM783,784, 785, TM910	See the above BCI		See the above BCI						
		-		SA30Y-17	3.0M	Adult, Fish clip	C8	NO	NO	
		-		SA30S-17	3.0M	Adult, Soft finger	D1	NO	NO	
	-		SA30M-17	3.0M	Adult, Multi-purpose	C8	NO	NO		
	TM7, Argus LCM, (*M tech)	1863/ LNCS DCI		C403-49*	1.1M	Adult, Fish clip	C4			
		1863/ LNCS DCI		C403S-49*	1.1M	Adult, Soft finger	C6			
		2258/ LNCS YI		C803-49*	1.1M	Adult, Multi-purpose	C4			
	-		SA30Y-17M*	3.0M	Adult, Fish clip	C8	NO	NO		
	-		SA30S-17M*	3.0M	Adult, Soft finger	D1	NO	NO		
	-		SA30M-17M*	3.0M	Adult, Multi-purpose	C8	NO	NO		
	Propaq CS, Encore, Micropaq (New) (M) (*M tech)	See M 1.1m		See M 1.1m						
		LNOP DC-12		SA30Y-15*	3.0M	Adult, Fish clip	C8	NO	NO	
LNOP DC-12			SA30S-15*	3.0M	Adult, Soft finger	D1	NO	NO		
-		SA30M-15*	3.0M	Adult, Multi-purpose	C8	NO	NO			



Product Service

# Certificate

No. Q5 088955 0005 Rev. 06

**Holder of Certificate:** **Shenzhen Caremed Medical Technology Co.,Ltd.**  
3/F, Building C  
Xiazao Digital Industrial Park  
No. 8 Huali Road, Gaofeng Community, Dalang Street  
Longhua district  
518109 Shenzhen  
PEOPLE'S REPUBLIC OF CHINA

## Certification Mark:



**Scope of Certificate:** **Design and Development, Production and Distribution of SpO2 sensors, Temperature probes, ECG cables and leadwires, EKG cables, Patient Cables and Invasive Blood Pressure cable, Accessories for Blood Pressure Measuring Devices, Fetal belt, Tourniquet, Pressure infusor bag, Tourniquet cuff, Reusable ECG electrode, EEG cables**

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 088955 0005 Rev. 06](http://www.tuvsud.com/ps-cert?q=cert:Q5_088955_0005_Rev.06)

**Report No.:** GZ25019201

**Valid from:** 2025-09-19  
**Valid until:** 2027-02-09

**Date,** 2025-09-19

Christoph Dicks  
Head of Certification/Notified Body



Product Service

# Certificate

No. Q5 088955 0005 Rev. 06

**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):** **Shenzhen Caremed Medical Technology Co.,Ltd.**  
3/F, Building C, Xiazao Digital Industrial Park, No. 8 Huali Road,  
Gaofeng Community, Dalang Street, Longhua district, 518109  
Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of SpO2 sensors, Temperature probes, ECG cables and leadwires, EKG cables, Patient Cables and Invasive Blood Pressure cable, Accessories for Blood Pressure Measuring Devices, Tourniquet, Reusable ECG Electrode  
Design, Development and Distribution of Fetal belt, Pressure infusor bag, Tourniquet cuff, EEG cables

**Jiangxi Caremed Medical Technology Co., Ltd**  
Building 15th, Venture Incubator Park, Industrial Park District,  
Xiajiang, 331400 Ji'an City, JiangXi Province, PEOPLE'S  
REPUBLIC OF CHINA

Production of SpO2 sensors, Temperature probes, ECG cables and leadwires, EKG cables, Patient Cables and Invasive Blood Pressure cable, Accessories for Blood Pressure Measuring Devices, Fetal belt, Tourniquet, Pressure infusor bag, Tourniquet cuff, Reusable ECG Electrode, EEG cables





## Confirmation Letter Template Regarding Amending Regulation (EU) 2023/607

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

Shenzhen Caremed Medical Technology Co., Ltd.  
3/F, Building C  
Xiazao Digital Industrial Park, No. 8 Huali Road  
Gaofeng Community, Dalang Street  
Longhua District  
518109 Shenzhen  
PEOPLE'S REPUBLIC OF CHINA

### TÜV SÜD Product Service GmbH

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
88955	GZ25019201	medical_devices@tuv süd.com	N/A	18 September 2025	1 of 6

### Confirmation Letter

**Reference: GZ25019201**

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: CN-MF-000010579

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables 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. This table is usually used if TÜV SÜD Product Service GmbH also certified the devices under Directives. In other cases (usually transfers from another Directives notified body), there are dependencies such as effective date of the transfer agreement. If the transfer agreement is not effective, the table 2 is more appropriate.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive. For example due to ongoing transfer of appropriate surveillance. This table is usually used if the client asks for confirmation of the application and the written agreement, but the transfer agreement for appropriate surveillance is not effective.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC



## Confirmation Letter Template Regarding Amending Regulation (EU) 2023/607

(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)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see <https://www.tuvsud.com/en/customer-hub/ps-cert/?q=CL+088955+0008>

In case of inquiries please contact [medical\\_devices@tuvsud.com](mailto:medical_devices@tuvsud.com).

On behalf of the Notified Body TÜV SÜD Product Service GmbH,  
18 September 2025

TÜV SÜD Product Service GmbH  
Medical and Health Services

TÜV SÜD Product Service GmbH  
Medical and Health Services

Handwritten signature of May Yuan in black ink.

May Yuan (18. September 2025 13:47:29 GMT+8)

May Yuan  
Conformity Assessment Responsible (CARE)

Handwritten signature of Wolfgang Oberprieler in black ink.

Wolfgang Oberprieler (18. September 2025 07:51:54 GMT+2)

Wolfgang Oberprieler  
Application Reviewer



## Confirmation Letter Template Regarding Amending Regulation (EU) 2023/607

**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:**

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
<b>SpO2 Sensor</b> (Basic UDI-DI: 69707585RSPA7)	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: G1 088955 0007 Rev. 01; NB# 0123 or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
<b>SpO2 Sensor</b> (Basic UDI-DI: 69707585DSP7Z)	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: G1 088955 0007 Rev. 01; NB# 0123 or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
<b>Temperature probe</b> (Basic UDI-DI: 69707585RSTP5Y)	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: G1 088955 0007 Rev. 01; NB# 0123 or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
<b>Temperature probe</b> (Basic UDI-DI: 69707585RGTP44)	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: G1 088955 0007 Rev. 01; NB# 0123 or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)



## Confirmation Letter Template Regarding Amending Regulation (EU) 2023/607

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
	<input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device		Evidence #1; CA# Evidence #2; CA#
<b>Temperature probe</b> (Basic UDI-DI: 69707585DSTP2W)	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: G1 088955 0007 Rev. 01; NB# 0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
<b>Temperature probe</b> (Basic UDI-DI: 69707585DGTPYX)	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A  or  <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: G1 088955 0007 Rev. 01; NB# 0123  or  <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



## Confirmation Letter Template Regarding Amending Regulation (EU) 2023/607

**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
Not applicable	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A



## Confirmation Letter Template Regarding Amending Regulation (EU) 2023/607

### Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2023/10/19	713267943	Initial issue
2025-09-18	GZ25019201	Change of site

**DECLARATION OF CONFORMITY  
TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993  
CONCERNING MEDICAL DEVICES**



**MANUFACTURER:** Shenzhen Caremed Medical Technology Co., Ltd.  
3/F, Building C, Xiazao Digital Industrial Park, No. 8 Huali Road,  
Gaofeng Community, Dalang Street, Longhua District,  
518109Shenzhen, PEOPLE'S REPUBLIC OF CHINA

**MEDICAL DEVICE:** Probes, Oximeter (Gmdns code 17594)

SpO2 sensor  
SEE ATTACHED LIST 1

**CLASSIFICATION - ANNEX IX:** CLASS IIB, RULE10

**CONFORMITY ASSESSMENT ROUTE:** ANNEX II.3

WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC and Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745.

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

**STANDARDS APPLIED:** SEE ATTACHED LIST 2

**NOTIFIED BODY:** TÜV SÜD PRODUCT SERVICE GMBH  
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

**IDENTIFICATION NUMBER**

**CE** 0123

**CERTIFICATE(S) No.:** CL 088955 0008 Rev.01



**EUROPEAN REPRESENTATIVE:**  
SUNGO EUROPE B.V.

ADD: FASCINATIO BOULEVARD 522, UNIT 1.7, 2909VA CAPELLE AAN DEN IJSSEL, THE NETHERLANDS

**START OF CE-MARKING:** 2015/2/10

**PLACE, DATE OF DECLARATION:** Shenzhen, 2026-1-14

**SIGNATURE:**

  
PRINT NAME: ALAN XIE

POSITION: QUALITY MANAGER

# Attachment1: Product Description

Manufacturer: **Shenzhen Caremed Medical Technology Co., Ltd.**  
 identification:

Application



**Part A:**

**1. Product Name**

Spo2 sensor

**2. Brief Introduction:**

The SpO2 sensor is indicated for use to measure the approximate, non-invasive and continuous arterial oxygen saturation and pulse rate of patients

**3. Principle and Operation Process:**

The compatible SpO2 sensor is indicated for use to measure the approximate, non-invasive and continuous arterial oxygen saturation and pulse rate of adult, infant, neonate& pediatric. The SpO2 sensor is designed to match the specifications of the original equipment manufacturer, therefore ensure the appropriate sensor model number is selected for a particular pulse oximeter technology.

**4. Intended Usage and Applicable Areas and Places:**

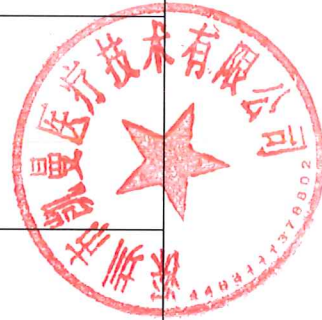
The compatible SpO2 sensor is indicated for use to measure the approximate, non-invasive and continuous arterial oxygen saturation and pulse rate of adult, infant, neonate& pediatric. The SpO2 sensor is designed to match the specifications of the original equipment manufacturer, therefore ensure the appropriate sensor model number is selected for a particular pulse oximeter technology.

**5. Models with Picture**

Model (In detail, pls see Appendix I and Appendix II)	Picture
SAXXY	
SAXXS	
SPXXY	

# Attachment1: Product Description

SPXXS	
SIXXS	
SNXXW	
SAXXM	
SAXXE	
SPXXT	
SAXXF	
SNXXN	



## Part B:

### 1. Classification Class IIb

# Attachment1: Product Description

2. **GMDN Code**  
17594

3. **Procedure for Certification**  
Rule 10 by MDD/93/42/EEC II.3



## Attached list 2 Standards cited

No.	Standard Name	Reference No.
1	Medical Device Quality System for the regulation requirement	ISO 13485:2016
2	Medical devices — Application of risk management to medical devices	ISO 14971:2019
3	Medical devices — Guidance on the application of ISO 14971	ISO/TR 24971:2020
3	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 15223-1:2021/Amd1:2025
4	Term, symbol and information of medical device— information of medical device manufacturer offering	EN 1041:2008+A1:2013
5	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance	IEC 60601-1:2005+AMD1:2012+AMD2:2020
6	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests	IEC 60601-1-2:2014+AMD1:2020
7	Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment	ISO 80601-2-61:2017+AMD1:2018
8	Clinical investigation of medical devices for human subjects - Good clinical practice	EN ISO 14155:2020+A11:2024
9	Medical devices - Part 1: Application of usability engineering to medical devices	EN 62366-1:2015
10	Biological evaluation of medical devices — Part 1: Evaluation and testing with a risk management process	ISO 10993-1:2018
11	Biological evaluation of medical devices — Part 5: Tests for in-vitro cytotoxicity	ISO 10993-5:2009
12	Biological evaluation of medical devices — Part 23: Tests for irritation	ISO 10993-23:2021
13	Biological evaluation of medical devices — Part 10: Tests for skin sensitization	ISO 10993-10:2021

