TÜVNORD

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Zertifikat / *Certificate*

TÜVNORD
TÜV NORD CERT GmbH
EN ISO 13485
tuev-nord.de

Hiermit wird bescheinigt, dass die Firma / *This certifies, that the company*

Andocor n.v.
Kruisblok 9
2320 Hoogstraten
Belgien

ein Qualitätsmanagementsystem nach der Norm DIN EN ISO 13485 : 2021 / EN ISO 13485:2016 + AC:2018 + A11:2021 - Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke (ISO 13485:2016) - eingeführt hat und aufrechterhält. Dieses Zertifikat stellt nicht den erforderlichen Nachweis zur Anbringung der CE-Kennzeichnung dar.

has established and maintains a quality management system that meets the requirements of DIN EN ISO 13485 : 2021 / EN ISO 13485:2016 + AC:2018 + A11:2021 - Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016). This certificate is not an authorisation to affix the CE mark.

Geltungsbereich / *Scope*

Design, manufacturing and sales of medical devices for cardiovascular surgery and anaesthesia:
Sterile cardiovascular cannulation devices,
Sterile cardioplegia devices,
Sterile gas diffusers

Reg.-Nr. / *Reg.-No.* 44 221 200262
Bericht Nr. / *Report No.* 3536 0391

Gültigkeit / *Validity*
von / *from* 2023-12-29
bis / *until* 2026-12-28
Edition 7

Essen, 2023-12-06 B. Hoy

Zertifizierungsstelle für Medizinprodukte / *Certification body for medical devices*

Visit our database to verify the validity of this certificate.

TÜV NORD CERT GmbH
Am TÜV 1, 45307 Essen
www.tuev-nord-cert.de
medical@tuev-nord.de
TÜV®

DAkkS Deutsche Akkreditierungsstelle D-ZM-12007-05-00

TÜVNORDGROUP

Add value.
Inspire trust.

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

Andocor N.V.
Kruisblok 9
2320 Hoogstraten
BELGIUM

Your reference/letter of	Our reference/name	Tel. extension/Email	Date	Page
125137	713337295	medical_devices@tuvsud.com	2024-07-26	1 of 5

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 125137 0001 Rev. 00

Reference: 713337295_CL

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: BE-MF-000003344

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.
- 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.

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)

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 www.tuvsud.com/ps-cert?q=cert:CL 125137 0001 Rev. 00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-07-26

TÜV SÜD Product Service GmbH
Medical and Health Services

Katarzyna Dziadosz (Jul 26, 2024 09:29 GMT+2)

Dziadosz, Katarzyna
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Matthias Mumme (Jul 26, 2024 09:28 GMT+2)

Matthias Mumme
Application Reviewer

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
N/A	☒ N/A	☒ N/A	☒ N/A

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is <u>NOT</u> 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
5420053400001N8	☒ Class III	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044
5420053400002NA	☒ Class III	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044
5420053400003NC	☒ Class III	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044
5420053400006NJ	☒ Class III	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044
5420053400007NL	☒ Class III	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044
5420053400009NQ	☒ Class III	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044
5420053400010N9	☒ Class III	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044
5420053400013NF	☒ Class III	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262;

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
			NB# 0044
5420053400016NM	☒ Class III	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044
5420053400017NP	☒ Class III	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044
5420053400018NR	☒ Class III	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044
5420053400022NG	☒ Class III	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044
5420053400026NQ	☒ Class III	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044
5420053400004NE	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044
5420053400005NG	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044
5420053400008NN	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044
5420053400011NB	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044
5420053400012ND	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044
5420053400014NH	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044
5420053400019NT	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate Reg.

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
			No. 44 232 200262; NB# 0044
5420053400020NC	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044
5420053400021NE	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044
5420053400023NJ	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044
5420053400024NL	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044
5420053400025NN	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-07-26	713337295	Initial issue

EG-Zertifikat / *EC-Certificate*

gem. 93/42/EWG Anhang II ohne (4) / *acc. 93/42/EEC Annex II without (4)*

Hiermit wird bescheinigt, dass die Firma / *This certifies, that the company*

Andocor N.V.
Kwikaard 104
2980 Zoersel
Belgium

für die Produkte / die Kategorie: Liste der Produkte siehe Anlage 1
for the products / product category: List of products see annex 1

Sterile kardiovaskuläre Einweg-Kanülen
Sterile Einweg-Kardioplegie-Produkte
Sterile Einweg-Blutleitungen zur Hämokonzentration mit oder ohne Hämofilter
Sterile Einweg-Gasdiffusoren
Sterile disposable cardiovascular cannulation devices
Sterile disposable cardioplegia devices
Sterile disposable bloodlines for haemoconcentration with or witout haemofilter
Sterile disposable gas diffusers

ein Qualitätssicherungssystem für die Auslegung, die Fertigung und die Endkontrolle der genannten Produkte nach Maßgabe des Anhang II (ohne Abschnitt 4) der Richtlinie 93/42/EWG anwendet. Zusätzlich zur CE-Kennzeichnung muss die Kennummer der Benannten Stelle angebracht werden. Die Gültigkeit dieses Zertifikats beruht auf der Aufrechterhaltung des Qualitätssicherungssystems in Übereinstimmung mit den Anforderungen der Richtlinie und seiner Überwachung durch die Benannte Stelle gem. Anhang II Abschnitt 5. Das Zertifikat ist unter keinen Umständen übertragbar.

has established a quality system for design, production and final testing acc. to the requirements of Annex II (without section 4) of the directive 93/42/EEC. Additional to the CE-marking the notification number of the Notified Body has to be affixed. The validity of this certificate is based on the maintenance of the quality system in accordance with the requirements of the directive and its surveillance by the Notified Body according Annex II section 5. The certificate may not be transferred under any circumstances.

Reg.-Nr. / *Reg.-No.* 44 232 200262
Bericht Nr. / *Report No.* 3528 2680

Gültigkeit / *Validity*
von / *from* 2021-05-25
bis / *until* 2024-05-26
Edition 2

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2021-05-25

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 44 232 200262

	Typ / *Type*	GMDN
Produkte der Klasse IIb / *Products of class IIb*		
Produkte zum Einmalgebrauch / *Single use Devices*	Hemoconcentrators	44602
	Set for haemoconcentration	44602
Produkte der Klasse IIa / *Products of class IIa*	Typ / *Type*	GMDN
Produkte zum Einmalgebrauch / Single use Devices	Arterial Cannula, reinforced	34893
	Arterial Cannula, non-reinforced	34893
	Aortic Catheter	34893
	Venous Catheter	34905
	Flex Line Venous Catheter	34905
	Two Stage Venous Catheter	34905
	Flex Line Two Stage Venous Catheter	34905
	Vent Catheters	46363
	Pericardial Sump	35917
	Rigid Sucker	35917

Bericht Nr. / *Report No.* 3528 2680

Gültigkeit / *Validity*
von / *from* 2021-05-25
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Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2021-05-25

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 44 232 200262

Produkte der Klasse IIa *Products of class IIa*	Typ *Type*	GMDN
Produkte zum Einmalgebrauch *Single use Devices*	Intracardiac Suckers	35917
	Yankauer Suction Tubes	35917
	Suction connecting tubes	16779
	Aspiration tubes	16779
	Vessel Cannulae	47798
	Connectors	61661
	Extremity Perfusion Cannulae	/
	Cannulation Tourniquet Set	58830
	Quick Prime Line	47889
	Aortic Root Cannulae	47799
	Retrograde Cardioplegia Cannula	36109
	Cardioplegia Set	58824
	Cardioplegia Needle	47799
	Ostial Perfusion Cannulae	34896
	Gas Diffuser	42977
	Hemoconcentrator Tubing Sets	44602

Bericht Nr. / *Report No.* 3528 2680

Gültigkeit / *Validity*
von / *from* 2021-05-25
Edition 2

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2021-05-25

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

ANLAGE / *ANNEX*

Reg.-Nr. / *Reg. No.* 44 232 200262

Produkte der Klasse Is *Products of class Is*	Typ *Type*	GMDN
Produkte zum Einmalgebrauch *Single use Devices*	Vent Plugs	/
	Vented Connector Caps	/
	Tubing Organizer	/
	Pressure Monitoring Line	61836

Anmerkung: Für Produkte der Klasse I steril beschränkt sich das Zertifizierungsverfahren auf die Aspekte der Herstellungsschritte in Zusammenhang mit der Sterilisation und der Aufrechterhaltung der Sterilität.
Note: *For products of class I sterile the certification process is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions.*

Bericht Nr. / *Report No.* 3528 2680

Gültigkeit / *Validity*
von / *from* 2021-05-25
Edition 2

Zertifizierungsstelle für Medizinprodukte
Certification body for medical devices

Essen, 2021-05-25

TÜV NORD CERT GmbH Langemarckstraße 20 45141 Essen www.tuev-nord-cert.de medical@tuev-nord.de

Benannte Stelle Kenn-Nr. 0044 / *Notified Body ID. No. 0044*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-236.10.16

TÜVNORD

TÜV NORD CERT GmbH · P.O. Box 10 32 61 · 45032 Essen · Germany

Andocor N.V.
Mr. Andy Lenaerts
Kruisblok 9
2320 Hoogstraten
Belgium

TÜV NORD CERT GmbH

Am TÜV 1
45307 Essen, Germany

Phone: +49 201 825-0
Fax: +49 201 825-2517

info.tncert@tuev-nord.de
tuev-nord-cert.com/en

TÜV®

Our / Your Reference	Contact	Direct Dial	Date
Reg. No. 44 232 200262 ZA 35357736	TÜV NORD CERT Medical E-Mail: medical@tuev-nord.de	Phone: -2236 Fax: -3243	23 February 2024

Schriftliche Bestätigung zur Korrektur oder Ergänzung von Informationen über gültige Bescheinigungen nach Richtlinie 93/42/EWG unter Berücksichtigung der Bestimmungen der Verordnung (EU) 2017-745, Artikel 120.

Written confirmation correcting or complementing information on valid certificates according to Directive 93/42/EEC taking into account the provisions of Regulation (EU) 2017-745, Article 120.

TÜV NORD CERT GmbH, Benannte Stelle für Medizinprodukte, Kennnummer 0044.
TÜV NORD CERT GmbH, Notified Body for medical devices, identification number 0044

Gemäß den Festlegungen in Verordnung (EU) 2017/745, Artikel 120, dürfen noch gültige, unter der Richtlinie 93/42/EWG ausgestellte Bescheinigungen nicht mehr geändert werden. Dieses Schreiben bestätigt Korrekturen oder Ergänzungen von Informationen an nachfolgender, gültiger Bescheinigung.

In accordance with the provisions of Regulation (EU) 2017/745, Article 120, certificates issued under Directive 93/42/EEC that are still valid may no longer be changed. This letter confirms correcting or complementing information of the following valid certificate.

Hersteller / *Manufacturer*

Andocor N.V.
Kruisblok 9
2320 Hoogstraten
Belgium

Konformitätsbewertungsverfahren / *Conformity assessment procedure*

93/42/EWG Anhang II ohne (4) / *93/42/EEC Annex II without (4)*

Reg.-Nr. / *Reg. No.*

44 232 200262

Bericht Nr. / *Report No.*

3534 2913
3534 5724

35357736

Ausstellungsdatum / *Date of issue*	Gültig ab / *Valid from*	Gültig bis / *Valid until*	Edition / *Edition*
2021-05-25	2021-05-25	2024-05-26	2
2023-01-31	2023-01-31	2024-05-26	Korrektur 001 / *Correction 001*
2023-04-05	2023-04-05	2024-05-26	Korrektur 003 / *Correction 003*
2024-02-23	2024-02-23	2024-05-26	Korrektur 004 / *Correction 004*

Änderungsgrund / *Reason of change*

Abmeldung des zu der Produktgruppe Gruppe Sterile Geräte zur kardiovaskulären Kannulierung gehörenden Produktes der Klasse IIa Suction connecting tubes (GMDN 16779)
De-registration of the product of class IIa Suction connecting tubes (GMDN 16779) *belonging to the product group sterile Cardiovascular cannulation devices*

Änderung / *Change*

Einschränkung der Bescheinigung um die Produktgruppe Sterile Geräte zur kardiovaskulären Kannulierung mit dem Produkt der Klasse IIa Suction connecting tubes (GMDN 16779)
Restriction of the certificate by the product group sterile Cardiovascular cannulation devices with the product of class IIa Suction connecting tubes *(GMDN 16779)*

Bestätigter Geltungsbereich / *Confirmed scope*

Sterile Einweg-Kardioplegie-Produkte
Sterile Einweg-Gasdiffusoren

Sterile disposable cardioplegia devices
Sterile disposable gas diffusers

TÜVNORD

Anlage 1, Reg.-Nr. / *Annex 1, Reg. No.*

44 232 200262

Bericht Nr. / *Report No.*

3534 2913
3534 5724

35357736

Ausstellungsdatum / *Date of issue*	Gültig ab / *Valid from*	Gültig bis / *Valid until*	Edition / *Edition*
2021-05-25	2021-05-25		2
2023-02-15	2023-02-15		Korrektur 002 / *Correction 002*
2023-04-05	2023-04-05		Korrektur 003 / *Correction 003*
2024-02-23	2024-02-23		Korrektur 004 / *Correction 004*

Änderungsgrund / *Reason of change*

Einschränkung der Bescheinigung um die Produktgruppe Sterile Geräte zur kardiovaskulären Kannulierung mit dem Produkt der Klasse IIa Suction connecting tubes (GMDN 16779)
Restriction of the certificate by the product group sterile Cardiovascular cannulation devices with the product of class IIa Suction connecting tubes *(GMDN 16779)*

Änderung / *Change*

Einschränkung der Bescheinigung um die Produktgruppe Sterile Geräte zur kardiovaskulären Kannulierung mit dem Produkt der Klasse IIa Suction connecting tubes (GMDN 16779)
Restriction of the certificate by the product group sterile Cardiovascular cannulation devices with the product of class IIa Suction connecting tubes *(GMDN 16779)*

Bestätigter Geltungsbereich / *Confirmed scope*

Produkte der Klasse IIa *Products of class IIa*	Typ *Type*	GMDN
Produkte zum Einmalgebrauch *Single use Devices*	Vent Catheters	46363
	Pericardial Sump Rigid Sucker Intracardiac Suckers Yankauer Suction Tubes	35917
	Vessel Cannulae	47798
	Connectors	61661
	Extremity Perfusion Cannulae	/
	Cannulation Tourniquet Set	58830
	Quick Prime Line	47889
	Aortic Root Cannulae Cardioplegia Needle	47799
	Retrograde Cardioplegia Cannula	36109
	Cardioplegia Set	58824
	Ostial Perfusion Cannulae	34896
Produkte zum Einmalgebrauch *Single use Devices*	Gas Diffuser	42977

Produkte der Klasse Is *Products of class Is*	Typ *Type*	GMDN
Produkte zum Einmalgebrauch *Single use Devices*	Vent Plugs	/
	Vented Connector Caps	/
	Tubing Organizer	/
	Pressure Monitoring Line	61836

Anmerkung: Für Produkte der Klasse I steril beschränkt sich das Zertifizierungsverfahren auf die Aspekte der Herstellungsschritte im Zusammenhang mit der Sterilisation und der Aufrechterhaltung der Sterilität.
Note: For products of class I sterile the certification process is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions.

Soweit zutreffend, werden Änderungen des Geltungsbereichs von Bescheinigungen, gemäß den Übergangsvorschriften nach § 96 MPDG, an das "Deutsche Medizinprodukte-Informations- und Datenbanksystem" (DMIDS) gemeldet.
Where applicable, changes to the scope of certificates are reported to the "German Medical Devices Information and Database System" (DMIDS), in accordance with the transitional provisions under Section 96 of the MPDG.

Digital unterschrieben von Akpossogna Kodjo Mensah
Datum: 2024.02.23 11:57:39 +01'00'

TÜV NORD CERT GmbH
Zertifizierungsstelle für Medizinprodukte
Certification Body for Medical Devices