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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	Fax extension	Date	Page
125137	0713338187	medical_devices@tuvsud.com		2024-09-30	1 of 5

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 125137 0001 Rev. 02

Reference: 0713338187

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that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

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-09-30

TÜV SÜD Product Service GmbH
Medical and Health Services

Katarzyna Dziadosz (30. September 2024 14:57 GMT+2)

Dziadosz, Katarzyna
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Fatlume Bahtiri (30. September 2024 14:58 GMT+2)

Fatlume Bahtiri
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
Andocor vent catheters **5420053400016NM** **Individual Article Numbers:** **SV16** **SV20** **EUSV40116G** **EUSV40120G**	☒ Class III	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044 **Note: TÜV SÜD takes over responsibility for appropriate surveillance on 2024-09-26**
Andocor vent catheters **5420053400013NF** **Individual Article Numbers:** **PVSO170** **PVSO171** **PVSO172** **PVSOG171** **PVSOR170** **PVSOR171** **PVSOR172** **PVSOR173** **PVSO180** **PVSO181** **PVSO182** **PVSOG181** **PVSOR180** **PVSOR181** **PVSOR182** **PVSB134** **PVSBG134** **PVSB155** **PVSBG170** **PVSBG171** **PVSBG172** **PVSBR170** **PVSBR171** **PVSBR172** **PVSB180** **PVSB181**	☒ Class III	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044 **Note: TÜV SÜD takes over responsibility for appropriate surveillance on 2024-09-26**

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
PVSB182 **PVSB185** **PVSB185A** **PVSBG180** **PVSBG181** **PVSBG182** **PVSBR180** **PVSBR181** **PVSBR182** **PVSB201** **PVSBG201** **PVSBR201** **PVSB215** **PVSB215A** **PVBA13** **PVBA20** **EUVCS90317** **EUVCS90318** **EUVCS90318R** **EUVCS90318G** **EUVCS40318** **EUVCS40318G** **EUVCS40318R** **EUVCS40320G** **EUVCS40320R** **EUVCA40313** **EUVCA40320**			
Andocor suckers and drains **5420053400011NB** **Individual Article Numbers:** **PS40** **PS40M** **PS40MH** **PS40ML** **PS40MLH** **PS40M1** **PS40M2** **PS40MLH2** **EUPS110316** **EUPS120316** **EUPS130316** **TC20B** **TC24B** **TC28B**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044 **Note: TÜV SÜD takes over responsibility for appropriate surveillance on 2024-09-26**

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
TC32B **TC20BC** **TC24BC** **TC28BC** **TC32BC** **TCS20B** **TCS24B** **TCS28B** **TCS32B** **TC20S** **TC24S** **TC28S** **TC32S** **TC20SC** **TC24SC** **TC28SC** **TC32SC** **TCS20S** **TCS24S** **TCS28S** **TCS32S**			
Andocor suckers and drains **5420053400019NT** **Individual Article Numbers:** **RS01** **RS02** **EURS100300**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044 **Note: TÜV SÜD takes over responsibility for appropriate surveillance on 2024-09-26**
Andocor suckers and drains **5420053400020NC** **Individual Article Numbers:** **FS300** **FS301** **EUFS100317**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044 **Note: TÜV SÜD takes over responsibility for appropriate surveillance on 2024-09-26**
Andocor blower/ mister **5420053400024NL** **Individual Article Number:**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044

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
BM001			**Note: TÜV SÜD takes over responsibility for appropriate surveillance on 2024-09-26**
Andocor vessel cannulae **5420053400014NH** **Individual Article Numbers:** **VC3** **VC3B** **EUVC90000FL** **EUVB90000FL**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044 **Note: TÜV SÜD takes over responsibility for appropriate surveillance on 2024-09-26**
Andocor vessel cannulae **5420053400021NE** **Individual Article Numbers:** **VC04** **EUVC90000R**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044 **Note: TÜV SÜD takes over responsibility for appropriate surveillance on 2024-09-26**
Andocor connectors **5420053400005NG** **Individual Article Numbers:** **04CS001** **04CS002** **04CS003** **04CS004** **04CS005** **04CS006** **04CS007** **04CS008** **04CS0012** **04CS0022** **04CS0032** **04CS0042** **04CS0052** **04CS0062** **04CS0072** **04CY001** **04CY002** **04CY003** **04CY004** **04CY005**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044 **Note: TÜV SÜD takes over responsibility for appropriate surveillance on 2024-09-26**

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
04CY006 **04CY007** **04CY008** **04CY009** **04CY0012** **04CY0022**			
Andocor Tourniquet Sets **5420053400012ND** **Individual Article Number:** **CT01** **CT02** **CT03** **CT04** **CT05** **CT06** **CT07** **CT08** **CT09** **CT10**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044 **Note: TÜV SÜD takes over responsibility for appropriate surveillance on 2024-09-26**
Andocor Tourniquet Sets **5420053400025NN** **Individual Article Number:** **VT01**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044 **Note: TÜV SÜD takes over responsibility for appropriate surveillance on 2024-09-26**
Andocor aortic root cannulae **5420053400002NA** **Individual Article Numbers:** **ARC01** **ARC01R** **ARC04** **ARC04R** **ARC07** **ARC07R** **ARC14** **ARC14V** **ARC02** **ARC02S**	☒ Class III	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044 **Note: TÜV SÜD takes over responsibility for appropriate surveillance on 2024-09-26**

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
ARC05 **ARC05S** **ARC08** **ARC08S** **ARC10** **ARC15** **ARC15S** **ARC01V** **ARC02V** **ARC04V** **ARC05V** **ARC07V** **ARC08V** **EUARS70010** **EUARS70008** **EUARS70007** **EUARL70008** **EUARS80010** **EUARS80008** **EUARS80007** **EUARS70007V** **EUARS70008V** **EUARS70010V** **EUARS80007V** **EUARS80008V** **EUARS80010V**			
Andocor retrograde cardioplegia cannulae **5420053400010N9** **Individual Article Numbers:** **RCC01** **EURC40014G**	☒ Class III	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044 **Note: TÜV SÜD takes over responsibility for appropriate surveillance on 2024-09-26**
Andocor cardioplegia adapters **5420053400004NE** **Individual Article Numbers:** **CSY03** **CSY03A** **CSY04** **CSY05** **CSY06** **CSY07**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044 **Note: TÜV SÜD takes over responsibility for appropriate surveillance on 2024-09-26**

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
CSY08 **CSY09** **CSY10** **CSY11** **CSY12** **CSY13** **CSY14** **CSY15** **CSY16** **CSY17** **CSY18** **CSY19** **CSY20** **CSY21** **CSY22** **CSY23** **CSY24** **CSY25** **EUCAL00003** **EUCAL00004** **EUCAL00005** **EUCAL00006** **EUCAL00007** **EUCAL00008** **EUCAL00009** **EUCAL00010** **EUCAL00011** **EUCAL00012** **EUCAL00013** **EUCAL00014** **EUCAL00015** **EUCAL00016** **EUCAL00017** **EUCAL00018** **EUCAL00019** **EUCAL00020** **EUCAL00021** **EUCAL00022** **EUCAL00023**			
Andocor cardioplegia adapters **5420053400023NJ** **Individual Article Number:** **M9354**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044 **Note: TÜV SÜD takes over responsibility for appropriate surveillance on 2024-09-26**

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
Andocor Cardioplegia Needle **5420053400026NQ** **Individual Article Numbers:** **CN16** **EUCN00016**	☒ Class III	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044 **Note: TÜV SÜD takes over responsibility for appropriate surveillance on 2024-09-26**
Andocor ostial perfusion cannulae **5420053400009NQ** **Individual Article Numbers:** **OC1045** **OC1090** **OC1245** **OC1290** **OC1445** **OC1490** **EUOP10010** **EUOP20010** **EUOP10012** **EUOP20012** **EUOP10014** **EUOP20014**	☒ Class III	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044 **Note: TÜV SÜD takes over responsibility for appropriate surveillance on 2024-09-26**
Andocor ostial perfusion cannulae **5420053400022NG** **Individual Article Numbers:** **OC04A** **OC05A** **OC06A** **OC07A** **OC08A** **OC04S** **OC05S** **OC06S** **OC07S** **OC08S** **EUOP9006SF** **EUOP9007SF**	☒ Class III	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044 **Note: TÜV SÜD takes over responsibility for appropriate surveillance on 2024-09-26**

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
Andocor gas diffuser **5420053400008NN** **Individual Article Numbers:** **GAS225** **GAS225DP** **GAS225F** **GAS225L** **GAS225L1** **GAS225W** **TEMGAS225** **EUGS130000**	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate Reg. No. 44 232 200262; NB# 0044 **Note: TÜV SÜD takes over responsibility for appropriate surveillance on 2024-09-26**

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
2024-07-26	713337295	Initial issue
2024-09-26	713338187	Products were transferred from Table 2 to Table 1
2024-09-30	713338187	Removal of the Basic-UDI-DI 5420053400001N8; 5420053400003NC; 5420053400006NJ; 5420053400007NL; 5420053400017NP; 5420053400018NR due to the restriction of the MDD certificate applied by TÜV Nord Cert GmbH.