



CERTIFICATE

EC Certificate No. 1434-MDD-384/2021
Full Quality Assurance System
Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Applied Medical Resources Corporation
22872 Avenida Empresa
Rancho Santa Margarita, California 92688
UNITED STATES

for the design, manufacture and final inspection of
medical devices, class IIa

**Sterile and non-sterile surgical instruments and accessories,
surgical access ports, catheters for vascular access, urology
and general surgery**

The list of medical devices covered by this certificate is provided in the annex 1, 2, 3, 4

complies with requirements
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 21.05.2021 to 26.05.2024

The date of issue of the Certificate: 21.05.2021

The date of the first issue of the Certificate: 12.04.2019



Issued under the Contract No. MD-47/2021
Application No: 655/2020
Certificate bears the qualified signature.
Warsaw, 21/05/2021
Module H2/3/4/5

Anna
Małgorzata
Wyroba
Vice-President
Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2021.05.21
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ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-384/2021

List of medical devices covered by the certificate:

Product Family	Product Sub-Group	Model/Type
Alexis Contained Extraction System	Alexis Contained Extraction System	GTBXX
Applied Anoscope	Anoscope	CNA21
Dilation Catheter	Cholangiography Catheter	C10xx
		CHO-040-xF
GelPOINT Path	Transanal Access Platform	CNOxx
	Transanal Access Platform with Insufflation Stabilization Bag	CNBxx
GELPOINT V-Path	GELPOINT V-Path Transvaginal Access Platform	C2A11
		C2A15
		C2A12
Insufflation Needles	Insufflation Needles	C22xx
Laparoscopic Access Systems	Disposable Fixation Trocars	CFxxx
		Disposable Trocars
	C07xx	
	CTFxx	
	C0Rxx	
	COQxx	
	CTRxx	
	CTSxx	
	CTBxx	
	CTNxx	
	DuraGold Plastic Reusable Cannulas	
	Stainless Steel Reusable Cannulas and Obturators	C04xx
		COExx
		COFxx
Kii Dissecting Balloon	C0Hxx	



Issued under the Contract No. MD-47/2021
 Application No: 655/2020
 Certificate bears the qualified signature.
 Warsaw, 21/05/2021

Anna
 Małgorzata
 Wyroba
 Vice-President

Elektronicznie
 podpisany przez Anna
 Małgorzata Wyroba
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ANNEX 2 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-384/2021

List of medical devices covered by the certificate:

Product Family	Product Sub-Group	Model/Type
Laparoscopic Instruments	Laparoscopic Graspers	C41xx
		C42xx
Pneumostasis Ports	Trocar Seals	C0Lxx
		C0600
		420206-xx
		400161-xx
Pneumostasis Ports and Kits	Alexis Laparoscopic system	C87xx
	GelPort Hand Access Laparoscopic System and GelPoint Advanced Access Platform	C8XX2CE
		CNGL2
		CNGL3
Retractors	Wound Protector/Retractors	G63xx
		C83xx
		C84xx
		C85xx
		HRxxx
Suction Irrigators	Epix Probes	C72xx
	Epix Suction Irrigation Tubing Sets	C6xxx
Surgical Clamps and Inserts	Stealth Surgical Clamp Inserts	A0Axx
		A0Cxx
		A0Gxx
	Surgical Clamp Inserts	G-xx00
		G-xx05
		G-xx55
		A080x
		G-xx50



Issued under the Contract No. MD-47/2021
 Application No: 655/2020
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 Warsaw, 21/05/2021

Anna
 Małgorzata
 Wyroba

Elektronicznie
 podpisany przez Anna
 Małgorzata Wyroba
 Data: 2021.05.21
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Vice-President



ANNEX 3 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-384/2021

List of medical devices covered by the certificate:

Product Family	Product Sub-Group	Model/Type
Surgical Clamps and Inserts	Stealth Surgical Clamps	A32xx
	Surgical Clamps	A33xx
Surgical Clips	Custom Surgical Spring Clip	G-60xx
		G-12xx
		AVD-6025
	Stealth Surgical Spring Clip	A160x
		A165x
	Surgical Handless Clamps	G-11xx
		A2201
	Surgical Spring Clip	A161x
A1801		
Tissue Retrieval System	Tissue Retrieval System	CD00x
Urology Introducer Sheaths Access Sheaths	Forte AxP Access Sheath	B73xx
	Forte AxP Access Sheath Size 1	B72xx
	Forte AxP Access Sheath Size 2	B70xx
	Forte AxP Access Sheath Size 3	B71xx
Vascular Catheters	Biliary Catheter	A47xx
		CB05xxx8
		CB062313
	Irrigation Catheter	IRR-xxx-xxF
		IRR-xxx-xF
	Latis Graft Cleaning Catheter	A4Gxx
	Python Embolectomy Catheter	A4E0x
		CE0xx0DR
Regular Tip Embolectomy Catheter	A440x	



Issued under the Contract No. MD-47/2021
Application No: 655/2020
Certificate bears the qualified signature.
Warsaw, 21/05/2021

Anna
Małgorzata
Wyroba
Vice-President

Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2021.05.21
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ANNEX 4 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-384/2021

List of medical devices covered by the certificate:

Product Family	Product Sub-Group	Model/Type
Vascular Catheters	Regular Tip Embolectomy Catheter	CE0xx0
	Spring Tip Embolectomy Catheter	A4F0x
		CE0xx0ST
	Thrombectomy Catheter	A45xx
CT0xx0xx		

CE 1434

Issued under the Contract No. MD-47/2021
Application No: 655/2020
Certificate bears the qualified signature.
Warsaw, 21/05/2021

Anna
Małgorzata
Wyroba
Vice-President

Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
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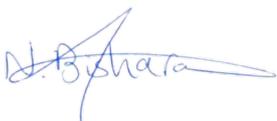
Amersfoort, June 2024

EU Medical Device Regulation (MDR) 2017/745
Extended Transitional Period

In March 2023, the European Commission approved an extension of Article 120 on transitional provisions in MDR. This extension allows, under certain criteria, for devices with expired EU Medical Device Directive (MDD) 93/42 CE certificates to be considered valid and to remain on the market until 2027 or 2028 depending on the risk class of the device, as described in Regulation EU 2023/607. This allows Applied Medical to make use of the above-mentioned transitional provisions.

This does not mean that MDD CE certificates will be updated with a new expiration date, but that after May 2024 Applied Medical's expired MDD CE certificates can still be considered valid. Applied Medical complies with the requirements set out in Article 120 in the MDR. Please see below the Applied Medical Manufacturer's Declaration and Notified Body Confirmation Letter regarding the extended transitional period.

Applied Medical is committed to the continuous supply of our products to you and your patients and is therefore working intensively on MDR certification and ensuring a smooth MDR transition of our products. We can confirm that the MDR certification activities are intensively ongoing with our Notified Body, and we can assure you our product will be MDR certified within the required timeframe.



Nesma Bishara
Director Regulatory Affairs and Quality Assurance

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*¹
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Applied Medical Resources Corp.
Manufacturer address and contact details	22872 Avenida Empresa, Rancho Santa Margarita, CA 92688
Single Registration Number (SRN)	US-MF-000000764

Authorised Representative name	Applied Medical Europe BV
Authorised Representative address and contact details	Wiekenweg 21, 3815 KL Amersfoort, The Netherlands
Single Registration Number (SRN)	NL-AR-000000044

Notified body name	Polish Centre for Testing and Certification
Notified body number	1434
Directive Certificate number(s) to which this confirmation is made (if applicable)	See attached schedule of devices
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	See attached schedule of devices
End date of extended validity/transition period	See attached schedule of devices

¹ The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

We, as the manufacturer declare under our sole responsibility:

- for the **Directive Certificates** (see attached schedule) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*²
- the listed **devices** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service, namely by fulfilling the following conditions:
 - **Directive Certificates** as listed in the attached schedule
 - Directive Certificates covering the listed devices were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterwards.
 - Formal applications to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the devices listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
 - **Upclassified devices**
 - In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:
 - Formal applications to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
 - **Quality Management System (QMS)**
 - A QMS in accordance with Article 10(9) MDR is in place.
 - **Device(s) as listed in the attached schedule**
 - The devices continue to comply with the MDD.
 - There are no significant changes in the design and intended purpose.
 - The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

² The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

Signed for and on behalf of the manufacturer:

Full Company Name: Applied Medical Resources Corp.

Location: 22872 Avenida Empresa, Rancho Santa Margarita, CA 92688

Date:

12SEP2023

Signature:



Name: Leilani Domingo

Title: Group Vice President, Regulatory Affairs

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Device Name	Model(s)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
Scope Warmer System	C3101	1434-MDD-382/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
	C300x	N/A	N/A	N/A	DQS 0297	December 31, 2028	N/A
Disposable Dissectors	CYxxx	1434-MDD-383/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
Epix Electrosurgical Probes with Smoke Evacuation	CW00x	1434-MDD-383/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
Laparoscopic Scissors System	CBxxx	1434-MDD-383/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
Voyant Bipolar Instruments	EB21X	1434-MDD-383/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
	EB230	1434-MDD-383/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
	EB240	1434-MDD-383/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
Voyant Electrosurgical Generator	EA020	1434-MDD-383/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
Surgical Clip Applier System	CA500	1434-MDD-383/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
Cholangiography Catheter	C1002	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
Transanal Access Platform with Insufflation Stabilization Bag	CNBxx	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
GELPOINT V-Path Transvaginal Access Platform	C2A11	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
	C2A12	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
	C2A15	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
Insufflation Needles	C22xx	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
Disposable Fixation Trocars	CFxxx	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
Disposable Trocars	CTFxx	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
	C0Rxx	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A

Disposable Trocars	C0Qxx	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
	CTRxx	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
	CTSxx	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
	CTBxx	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
Kii Dissecting Balloon	C0Hxx	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
Laparoscopic Graspers	C41xx	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
Reusable Grasper Handle	C5223	N/A	N/A	N/A	DQS 0297	December 31, 2028	N/A
GelPort Hand Access Laparoscopic System	C8XX2CE	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
GelPoint Advanced Access Platform	CNGL2	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
	CNGL3	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
Alexis Contained Extraction System	GTBXX	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
Wound Protector/Retractors	G63xx	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
	C83xx	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
	C84xx	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
	C85xx	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
	HRxxx	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
Tissue Retrieval System	CD00x	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
Epix Probes	C72xx	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
Epix Suction Irrigation Tubing Sets	C6xxx	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
Malleable Occlusion Reusable Handle	A3400	N/A	N/A	N/A	DQS 0297	December 31, 2028	N/A
Stealth Surgical Clamp Inserts	A0Axx	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2027	N/A
	A0Cxx	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2027	N/A
	A0Gxx	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2027	N/A
Surgical Clamp Inserts	G-xx00	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2027	N/A
	G-xx05	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2027	N/A
	G-xx55	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2027	N/A
	A080x	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2027	N/A
	G-xx50	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2027	N/A

Stealth Surgical Clamps	A32xx	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2027	N/A
Surgical Clamps	A33xx	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2027	N/A
Custom Surgical Spring Clip	G-60xx	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
	G-12xx	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
	AVD-6025	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
Stealth Surgical Spring Clip	A160x	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
	A165x	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
Surgical Handless Clamps	G-11xx	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
	A2201	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
Surgical Spring Clip	A161x	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A
	A1801	1434-MDD-384/2021	May 26, 2024	PCBC 1434	DQS 0297	December 31, 2028	N/A

Applied Medical Resources Corp.
22872 Avenida Empresa,
Rancho Santa Margarita, CA 92688
United States of America

16.05.2024

Notified Body Confirmation Letter
Reference: 549830

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 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DQS Medizinprodukte GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 on NANDO, has 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 following manufacturer:

Applied Medical Resources Corp.
22872 Avenida Empresa,
Rancho Santa Margarita, CA 92688
United States of America
SRN Number: US-MF-000000764

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 the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive from 26 September 2024. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

The transition timelines 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 (as amended by (EU) 2023/607), 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 excluding Well-established technologies (WET - 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 or have a 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)

On behalf of the Notified Body,



Alexander Hohn

Regulatory Affairs Manager

Table 1: Devices covered by this letter and for which the NB 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 at the pre-application stage)	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
Alexis Contained Extraction System	Class IIa	N/A	1434-MDD-384/2021 NB #1434
Kii Trocar Access Systems	Class IIa	N/A	1434-MDD-384/2021 NB #1434
Alexis Wound Retractors	Class IIa	N/A	1434-MDD-384/2021 NB #1434
Voyant Electrosurgical Generator	Class IIb (non-implanatable)	N/A	1434-MDD-383/2021 NB #1434
Voyant Electrosurgical Instruments	Class IIb (non-implanatable)	N/A	1434-MDD-383/2021 NB #1434
Epix Universal Clip Applier	Class IIb (implanatable)	N/A	1434-MDD-383/2021 NB #1434
GelPoint V-Path Transvaginal Access Platform	Class IIa	N/A	1434-MDD-384/2021 NB #1434
GelPort Hand Access Laparoscopic System	Class IIa	N/A	1434-MDD-384/2021 NB #1434

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	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
GelPOINT Advanced Access Platform and GelPOINT Mini Advanced Access Platform	Class IIa	N/A	1434-MDD-384/2021 NB #1434
GelPoint Path Transanal Access Platform	Class IIa	N/A	1434-MDD-384/2021 NB #1434
Epix Suction Irrigation System	Class IIa	N/A	1434-MDD-384/2021 NB #1434
Kii Dissecting Balloon	Class IIa	N/A	1434-MDD-384/2021 NB #1434
Epix Laparoscopic Scissors System	Class IIb (non-implanatable)	N/A	1434-MDD-383/2021 NB #1434
Epix Laparoscopic Dissector	Class IIb (non-implanatable)	N/A	1434-MDD-383/2021 NB #1434
Laparoscopic Graspers	Class IIa	N/A	1434-MDD-384/2021 NB #1434
Tissue Retrieval System	Class IIa	N/A	1434-MDD-384/2021 NB #1434
Insufflation Needles	Class IIa	N/A	1434-MDD-384/2021 NB #1434
Scope Warmer System (Seal)	Class I devices placed on the market in sterile condition	N/A	1434-MDD-382/2021 NB #1434
Aerostat Cholangiography Catheter	Class IIa	N/A	1434-MDD-384/2021 NB #1434
Surgical Clamps & Inserts	Class III	N/A	1434-MDD-384/2021 NB #1434
Epix Electrosurgical Probes with Smoke Evacuation	Class IIb (non-implanatable)	N/A	1434-MDD-383/2021 NB #1434
Surgical Clips & Clip Applicator (Surgical Clips)	Class IIa	N/A	1434-MDD-384/2021 NB #1434

Table 2: Devices covered by this letter and for which the NB 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 at the pre-application stage)	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
Surgical Clips & Clip Applicator (Clip Applicator)	Class I (reusable)	N/A	N/A – Class I under MDD

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
07.03.2024	549830-1	Initial issue

Date	NB internal reference traceable to each version of the letter	Action
22.03.2024	549830-1	Update to include additional devices in Table 2
16.05.2024	549830-2	Update to include additional devices and move applicable scope from Table 2 to Table 1

NB 0297