ASTER MEDISPRO PRIVATE LIMITED
S.P.181, 10th Main, 1st Stage Dr.B.R.Ambedkar
Industrial Estate (Kssidc), Jigani Industrial Area,
560105, Bangalore, Karnataka, India

Date: 17 May 2024

Confirmation Letter
Reference: IN_013179_2024_01c

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, HTCert, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2803 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:

ASTER MEDISPRO PRIVATE LIMITED
S.P.181, 10th Main, 1st Stage Dr.B.R.Ambedkar
Industrial Estate (Kssidc), Jigani Industrial Area,
560105 Bangalore, Karnataka, India
SRN: IN-MF-000013179

Digitally signed by Bunic Gheorghe
Date: 2025.05.31 10:40:21 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Application ID: IN013179 2024 02 01
Application Date: 13/05/2024
Contract for MDR certification signed on 17/05/2024.

The devices covered by the formal application and the written agreement mentioned above are identified below. HTCert has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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, by the 20 Mar 2023 for the relevant devices.

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,

Filippos Kottis
Certification Director

Devices covered by this letter

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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
URETERAL CATHETER	Class IIa	n/a	0068/QCO-DM/244-2020 NB 0068
MALECOT CATHETER	Class IIa	n/a	0068/QCO-DM/244-2020 NB 0068
PCN CATHETER	Class IIa	n/a	0068/QCO-DM/244-2020 NB 0068
PCN CATHETER WITH NEEDLE	Class IIa	n/a	0068/QCO-DM/244-2020 NB 0068
SUPRAPUBIC CATHETER	Class IIa	n/a	0068/QCO-DM/244-2020 NB 0068
CIC CATHETER	Class IIa	n/a	0068/QCO-DM/244-2020 NB 0068
TIEMANN CATHETER	Class IIa	n/a	0068/QCO-DM/244-2020 NB 0068
RE-ENTRY MALECOT CATHETER	Class IIa	n/a	0068/QCO-DM/244-2020 NB 0068
PCN CATHETER SET	Class IIa	n/a	0068/QCO-DM/244-2020 NB 0068
MALECOT CATHETER SET	Class IIa	n/a	0068/QCO-DM/244-2020 NB 0068

URODYNAMIC CATHETER	Class IIa	n/a	0068/QCO-DM/244-2020 NB 0068
AMPLATZ SHEATH	Class IIa	n/a	0068/QCO-DM/244-2020 NB 0068
URETERAL DILATOR	Class IIa	n/a	0068/QCO-DM/245-2020 NB 0068
FASCIAL DILATOR	Class IIa	n/a	0068/QCO-DM/245-2020 NB 0068
NOTTINGHAM DILATOR	Class IIa	n/a	0068/QCO-DM/245-2020 NB 0068
MEATAL DILATOR	Class IIa	n/a	0068/QCO-DM/245-2020 NB 0068
URETERAL BALLOON DILATION CATHETER	Class IIa	n/a	0068/QCO-DM/245-2020 NB 0068
AMPLATZ RENAL DILATOR SET	Class IIa	n/a	0068/QCO-DM/245-2020 NB 0068
URETHRAL FILLIFORM DILATOR	Class IIa	n/a	0068/QCO-DM/245-2020 NB 0068
URETHRAL DILATOR	Class IIa	n/a	0068/QCO-DM/245-2020 NB 0068
RENAL DILATOR	Class IIa	n/a	0068/QCO-DM/245-2020 NB 0068
BIOPSY NEEDLE	Class IIa	n/a	0068/QCO-DM/284-2021 NB 0068
BIOPSY GUN	Class IIa	n/a	0068/QCO-DM/284-2021 NB 0068
STONE BASKET STAINLESS STEEL	Class IIa	n/a	0068/QCO-DM/246-2020 NB 0068
STONE BASKET NITINOL	Class IIa	n/a	0068/QCO-DM/246-2020 NB 0068
STONE GRASPER	Class IIa	n/a	0068/QCO-DM/246-2020 NB 0068
STENT REMOVER	Class IIa	n/a	0068/QCO-DM/246-2020 NB 0068
URETERAL STENT/DOUBLE J STENT	Class IIa	n/a	0068/QCO-DM/283-2021 NB 0068
LOOP STENT	Class IIa	n/a	0068/QCO-DM/283-2021 NB 0068
PROSTATE STENT	Class IIa	n/a	0068/QCO-DM/283-2021 NB 0068
ENDOPYELOTOMY STENT	Class IIa	n/a	0068/QCO-DM/283-2021 NB 0068
TUMOR STENT	Class IIa	n/a	0068/QCO-DM/283-2021 NB 0068

MONO J STENT	Class IIa	n/a	0068/QCO-DM/283-2021 NB 0068
URETHRAL STENT	Class IIa	n/a	0068/QCO-DM/283-2021 NB 0068
GUIDEWIRE	Class IIa	n/a	0068/QCO-DM/283-2021 NB 0068
LONG PUSHER FOR DJS	Class IIa	n/a	0068/QCO-DM/283-2021 NB 0068
BLADDER EVACUATOR	Class IIa	n/a	0068/QCO-DM/246-2020 NB 0068
TRACK FINDER BULB IRRIGATOR	Class IIa	n/a	0068/QCO-DM/246-2020 NB 0068
TOOMEY TIP SYRINGE	Class IIa	n/a	0068/QCO-DM/246-2020 NB 0068
TUR SET (TUR LOOP)	Class IIa	n/a	0068/QCO-DM/246-2020 NB 0068
URETERAL ACCESS SHEATH	Class IIa	n/a	0068/QCO-DM/244-2020 NB 0068
INITIAL PUNCTURE NEEDLE	Class IIa	n/a	0068/QCO-DM/284-2021 NB 0068
FASCIAL DILATOR SET	Class IIa	n/a	0068/QCO-DM/245-2020 NB 0068
URETERAL DILATOR SET	Class IIa	n/a	0068/QCO-DM/245-2020 NB 0068

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/17	IN_013179_2024_01	Initial issue
2024/05/17	IN_013179_2024_01c	Typo correction in Certificate Number

CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QCO-DM/244-2020

according to Annex II of Directive 93/42/EEC on Medical Devices as amended

MTIC Intercert hereby declares that an examination of the under mentioned Full Quality Assurance System has been carried out following the requirements of the legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on Medical Devices. **MTIC Intercert certifies that the Full Quality Assurance System conforms with the relevant provisions of the aforementioned legislation. The validity of this certificate is subjected to the positive result of required surveillance audits.**

MANUFACTURER: **Aster Medispro Private Limited**

S.P.181, 10th Main Road, 1st Stage, Dr. B. R. Ambedkar Industrial Estate, Jigani Industrial Area, Jigani, Bangalore – 560 105, Karnataka (INDIA)

DEVICE/S: **Urology Catheters**

MODEL/S:

- ✓ **Ureteral Catheter with variants:**
  Close Tip (CT), Open Tip (OT), Angle Tip (AT), Cone Tip (CT), Whistle Tip (WT)

✓ Malecot Catheter	✓ PCN Catheter	✓ PCN Catheter With Needle
✓ Suprapubic Catheter	✓ CIC Catheter	✓ Tiemann Catheter
✓ Re-Entry Malecot Catheter	✓ PCN Catheter Set	✓ Malecot Catheter Set
✓ Urodynamic Catheter	✓ Amplatz Sheath	✓ Ureteral Access Sheath

FIRST ISSUE: **03/12/2020** CURRENT ISSUE: **03/12/2020** REVISION Nr.: **00** EXPIRING DATE: **27/05/2024**

Dipl.- Ing. Feridoon Sergizzarea
MTIC INTERCERT Certification Body

MTIC INTERCERT S.r.l. - Via Moscova, 11 - 20017 RHO (MI) - ITALY
www.mticert.org

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Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*
- 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	ASTER MEDISPRO PRIVATE LIMITED
Manufacturer address and contact details	Address: S.P.181, 10th Main, 1st stage Dr. B. R Ambedkar Industrial Estate(KSSIDC) Jigani Industrail Area, Jigani, Bangalore-560105. Contact Person: Manikandan Thachat Contact Number: 9845094645
Single Registration Number (SRN) (if available)	IN-MF-000013179

Authorised Representative name (if applicable)	CMC MEDICAL DEVICES & DRUGS S.L
Authorised Representative address and contact details	C/ Horacio Lengo no 18, CP 29006, Málaga, Spain. Contact Person: MANUEL MATEOS Contact Number: +34951214054
Single Registration Number (SRN) (if available)	ES-AR-000000293

Notified body name (if applicable)	MTIC INTERCERT S.R.L.
Notified body number (if applicable)	0068
Directive Certificate number(s) to which this confirmation is made (if applicable)	Urology Catheters - 0068/QCO-DM/244-2020 Urology Dilator - 0068/QCO-DM/245-2020 Urology Retrievers - 0068/QCO-DM/246-2020 Urology Stents - 0068/QCO-DM-283-2021 Urology Biopsy Products - 0068/QCO-DM/284-2021
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26.05.2024
End date of extended validity/transition period	31.12.2028

ASTER MEDISPRO PRIVATE LIMITED
AN ISO, EN ISO, ICMED - 13485, CE Certified Company
S.P. 181, 10th Main, 1st Stage, (KSSIDC), Dr. B.R. Ambedkar Industrial Estate,
Jigani Industrial Area, Bengaluru - 560 105, Karnataka, India.
Phone : +91 80 - 29795550 | **Mobile :** +91 98450 94645 | **Email :** info@astermedispro.net
Website : www.astermedispro.net | **CIN No :** U24239KA2001PTC029556 | **GSTIN :** 29AADCA3163A1Z5

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*
- the listed **device(s)** 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 Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was / were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/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 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.

  We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

ASTER MEDISPRO PRIVATE LIMITED
AN ISO, EN ISO, ICMED - 13485, CE Certified Company
S.P. 181, 10th Main, 1st Stage, (KSSIDC), Dr. B.R. Ambedkar Industrial Estate,
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Phone : +91 80 - 29795550 | **Mobile :** +91 98450 94645 | **Email :** info@astermedispro.net
Website : www.astermedispro.net | **CIN No :** U24239KA2001PTC029556 | **GSTIN :** 29AADCA3163A1Z5

☑ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/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 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.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 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:

Choose one applicable statement:

☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/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.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☑ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) 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.

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Signed for and on behalf of the manufacturer:

Full Company Name: ASTER MEDISPRO PRIVATE LIMITED

Location: S.P.181, 10th Main, 1st stage Dr. B. R Ambedkar Industrial Estate(KSSIDC) Jigani Industrail Area, Jigani, Bangalore-560105

Date: 20/05/2024

Name: Manikandan Thachat

Designation: Managing Director

Signature:

Contact Details:

Mail ID: manikandan@astermedispro.net

Contact Number: +91 9845094645

ASTER MEDISPRO PRIVATE LIMITED

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Schedule of Devices

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

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	**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)
Urology Catheters	0068/QCO-DM/244-2020	26.05.2024	MTIC - 0068	HT Cert - 2803	31.12.2028	NA
Urology Dilators	0068/QCO-DM/245-2020	26.05.2024	MTIC - 0068	HT Cert - 2803	31.12.2028	NA
Urology Retrievers	0068/QCO-DM/246-2020	26.05.2024	MTIC - 0068	HT Cert - 2803	31.12.2028	NA
Urology Stents	0068/QCO-DM-283-2021	26.05.2024	MTIC - 0068	HT Cert - 2803	31.12.2028	NA
Urology Biopsy Products	0068/QCO-DM/284-2021	26.05.2024	MTIC - 0068	HT Cert - 2803	31.12.2028	NA

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