

**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

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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