CERTIFICATE

PRODUCTION QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QPZ-DM/247-2020

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

MTIC Intercert hereby declares that an examination of the under mentioned firm production quality system has been carried out following the requirements of the legislation to which the undersigned is subjected, transposing annex V of the Directive 93/42/EEC on Medical Devices.

MTIC Intercert certifies that the production quality 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: **Medihub Sciencetec Private Limited**

Plot No 4, NH-7, MMDA Industrial Estate, Maraimalai Nagar – 603 209 Tamil Nadu (INDIA)

DEVICE/S: **Cardiac Surgery Devices**

MODEL/S: *see list of all models in annex 1*

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

This certificate is also made of n. 1 annex of n. 2 pages.

Dipl.- Ing. Feridoon Sergizzarea
MTIC INTERCERT Certification Body

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

CERTIFICATE

ANNEX No. 1 TO THE FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QPZ-DM/247-2020

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

Cardiac Surgery Devices

	Device Description	Code	Product Name	Model	Product Code
✓	Cardiotomy Reservoir	CR	Cardiotomy Reservoir	2 Litre	M7C-Adult
		CR	Cardiotomy Reservoir	3 Litre	M4C
✓	Myocardial Protection System	MPS	MMPs-01-Myocardial Protection System	Adult	M15MP
		MPS	Myocardial Protection System – Paediatric	Paediatric	M16Mp
		MPS	Myocardial Protection System –W/o RT	Adult	M17MP
		MPS	Myocardial Protection System – M20	Adult	M20MP
		MPS	Myocardial Protection System – M22	Adult	M22MP
		MPS	Myocardial Protection System – M24	Adult	M24MP
		MPS	Myocardial Protection System – M23	Adult	M23MP
✓	Cardioplegia Delivery System with and without delivery set	CPDS	Cardioplegia Delivery System	2 Litre	M8cp
✓	Arterial Blood Filter with and without Bypass Loop	ABF	Arterial Blood Filter with Loop	Adult	M5AF
		ABF	Arterial Blood Filter without Loop	Adult	M6AF
✓	Adult & Infant/ Paediatric Bubble Trap	ABT	Bubble Trap Adult with Loop	Adult	M7AB
		ABT	Bubble Trap Adult without Loop	Adult	M8AB
		ABT	Bubble Trap Adult Low Prime	Semi Adult	M6AB
		IBT	Infant Bubble Trap	Infant	M5IB
		PBT	Bubble Trap Paediatrics with Loop	Paediatrics	M6PB
		PBT	Bubble Trap Paediatrics without Loop	Paediatrics	M7PB

FIRST ISSUE OF THE CERTIFICATE:	03/12/2020	CURRENT ISSUE OF THE CERTIFICATE:	03/12/2020	CERTIFICATE IN REVISION Nr.:	00	EXPIRING DATE OF THE CERTIFICATE:	27/05/2024

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n. 0068/QPZ-DM/247-2020

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

Cardiac Surgery Devices

Device Description	Code	Product Name	Model	Product Code
✓ Perfusion Custom Pack	CPACK	Custom Pack	Adult	Based on Circuit
	CPACK	Custom Pack	Paediatric	Based on Circuit
	CPACK	Custom Pack	Infant	Based on Circuit
	CPACK	Custom Pack	Neonatal	Based on Circuit

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Add value.
Inspire trust.

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MEDIHUB SCIENCETEC PRIVATE LIMITED
Plot No.4, NH-7, MMDA Industrial Estate
Maraimalai Nagar, Tamil Nadu 603 209
INDIA

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
125790	713341973	medical_devices@tuvsud.com		2024-08-27	1 of 3

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 125790 0001 Rev. 00

Reference: 713341973

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: IN-MF-000007056

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 125790 0001 Rev. 00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-08-27

TÜV SÜD Product Service GmbH
Medical and Health Services

RAVI H A
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Andreas Reindl
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
Cardiopulmonary bypass cardiotomy suction line blood filter (890617223CPBCRDJ)	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #1; NB# 0068/QPZ-DM/247-2020; MTIC Intercert
Cardiopulmonary bypass heat exchanger (890617223CPBMPSH9/ 890617223CPBCPDSMA)	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #1; NB# 0068/QPZ-DM/247-2020; MTIC Intercert
Perfusion Custom pack (890617223CPBPPACK3X)	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #1; NB# 0068/QPZ-DM/247-2020; MTIC Intercert
Arterial Line Blood Filter (890617223CPBABFD9)	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #1; NB# 0068/QPZ-DM/247-2020; MTIC Intercert
Cardio pulmonary bypass defoamer (890617223CPBBTRAP2S)	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate #1; NB# 0068/QPZ-DM/247-2020; MTIC Intercert

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
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
2024-08-27	713341973	Initial issue