



Confirmation Statement on device(s) covered by EU Quality Management System Certificate (MDR)

No. GRD 125790 0004 Rev. 00

Manufacturer: **MEDIHUB SCIENCETEC PRIVATE LIMITED**
Plot No.4, NH-7, MMDA Industrial Estate
Maraimalai Nagar, Tamil Nadu 603209
INDIA

This Confirmation Statement is only valid in combination with: G15 125790 0003 Rev. 00

This Confirmation Statement confirms device(s) covered by the aforementioned EU Quality Management System Certificate (MDR). It considers clarification of device(s) covered by the device group(s). For details and confirmation statement validity see:

www.tuvsud.com/ps-cert?q=cert:GRD 125790 0004 Rev. 00

Report No.: TPS3337

Christoph Dicks
Head of Certification/Notified Body

Issue Date: 2026-06-15



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Device(s):

S.No	Medical Device Name
1	Arterial Line Blood Filter (Adult)
2	Cardio pulmonary bypass defoamer (Adult Bubble Trap)
3	Cardio pulmonary bypass defoamer (Infant/ Paediatric Bubble Trap)
4	Cardiopulmonary bypass cardiomy suction line blood filter :(Cardiotomy Reservoir 2 Liter)
5	Cardiopulmonary bypass cardiomy suction line blood filter: (Cardiotomy Reservoir 3 Liter)
6	Cardiopulmonary bypass heat exchanger : (Cardioplegia delivery system)
7	Cardiopulmonary bypass heat exchanger : (Myocardial Protection System)
8	Perfusion Custom pack