



C E R T I F I C A T E

FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QCO-DM/065-2018

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:

ARES MEDİKAL SAN. TİC. LTD. ŞTİ.

5821/1 Sk. No:6 Asık Veysel Mh. Karabaglar - 35110 İZMİR (TURKEY)

DEVICE/S:

- ✓ Hemodialysis catheter kits;
- ✓ Angiographic syringe, connecting tubing, hemostasis valve set;
- ✓ Introducer sets, guide wires, introducer needles;

MODEL/S:

full list of models in annex 1

FIRST ISSUE: 15/10/2018

CURRENT ISSUE: 20/03/2020

REVISION Nr.: 01

EXPIRING DATE: 14/10/2023

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

Dipl.- Ing. Feridoon Sergizzarea
MTIC/INTERCERT Certification Body



C E R T I F I C A T E

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

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Hemodialysis catheter kits

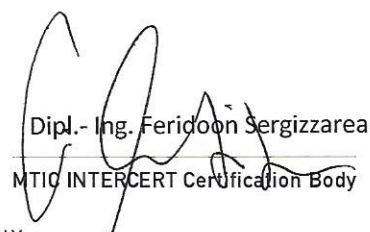
✓ HCT10001	✓ HCT10021	✓ HCT10041	✓ HCT10061	✓ HCT10081
✓ HCT10002	✓ HCT10022	✓ HCT10042	✓ HCT10062	✓ HCT10082
✓ HCT10003	✓ HCT10023	✓ HCT10043	✓ HCT10063	✓ HCT10083
✓ HCT10004	✓ HCT10024	✓ HCT10044	✓ HCT10064	✓ HCT10084
✓ HCT10005	✓ HCT10025	✓ HCT10045	✓ HCT10065	✓ HCT10085
✓ HCT10006	✓ HCT10026	✓ HCT10046	✓ HCT10066	✓ HCT10086
✓ HCT10007	✓ HCT10027	✓ HCT10047	✓ HCT10067	✓ HCT10087
✓ HCT10008	✓ HCT10028	✓ HCT10048	✓ HCT10068	✓ HCT10088
✓ HCT10009	✓ HCT10029	✓ HCT10049	✓ HCT10069	✓ HCT10089
✓ HCT10010	✓ HCT10030	✓ HCT10050	✓ HCT10070	✓ HCT10090
✓ HCT10011	✓ HCT10031	✓ HCT10051	✓ HCT10071	✓ HCT10091
✓ HCT10012	✓ HCT10032	✓ HCT10052	✓ HCT10072	✓ HCT10092
✓ HCT10013	✓ HCT10033	✓ HCT10053	✓ HCT10073	✓ HCT10093
✓ HCT10014	✓ HCT10034	✓ HCT10054	✓ HCT10074	✓ HCT10094
✓ HCT10015	✓ HCT10035	✓ HCT10055	✓ HCT10075	✓ HCT10095
✓ HCT10016	✓ HCT10036	✓ HCT10056	✓ HCT10076	✓ HCT10096
✓ HCT10017	✓ HCT10037	✓ HCT10057	✓ HCT10077	✓ HCT10097
✓ HCT10018	✓ HCT10038	✓ HCT10058	✓ HCT10078	✓ HCT10098
✓ HCT10019	✓ HCT10039	✓ HCT10059	✓ HCT10079	✓ HCT10099
✓ HCT10020	✓ HCT10040	✓ HCT10060	✓ HCT10080	✓ HCT10100

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Introducer sets	Guide wires	Introducer needle	Angiographic syringe	Connecting tubing	Hemostasis valve set
✓ IS9000	✓ GW2101	✓ IN4000	✓ AS8000	✓ CT1101	✓ HVS3000
✓ IS9001	✓ GW2102	✓ IN4001	✓ AS8001	✓ CT1102	✓ HVS3001
✓ IS9002	✓ GW2103	✓ IN4002	✓ AS8002	✓ CT1103	✓ HVS3002
✓ IS9003	✓ GW2104	-----	✓ AS8003	✓ CT1104	✓ HVS3003
✓ IS9004	✓ GW2105		✓ AS8004	✓ CT1105	✓ HVS3004
✓ IS9005	✓ GW2106		✓ AS8005	✓ CT1106	-----
✓ IS9006	✓ GW2107		✓ AS8006	✓ CT1107	
✓ IS9007	✓ GW2108		✓ AS8007	✓ CT1108	
✓ IS9008	✓ GW2109		✓ AS8008	✓ CT1201	
✓ IS9009	✓ GW2201		✓ AS8009	✓ CT1202	
✓ IS9010	✓ GW2202		✓ AS8010	✓ CT1203	
✓ IS9011	✓ GW2203		-----	✓ CT1204	
✓ IS9012	✓ GW2204			✓ CT1205	
✓ IS9013	✓ GW2205			✓ CT1206	
✓ IS9014	✓ GW2206			✓ CT1207	
✓ IS9015	✓ GW2207			✓ CT1208	
✓ IS9016	✓ GW2208			✓ CT1209	
✓ IS9017	✓ GW2209			-----	

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