Certificate of CE-Registration

This is to certify that, in accordance with the Medical Device Directive 93/42/EEC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

Ares Medikal San.Tic.Ltd.Sti.
Asik Veysel Mah 5821/1 sk. No:6
35110 Karabaglar - Izmir
TURKEY

as stipulated and demanded by the aforementioned Directive. The German Competent Authority has allocated the medical devices of the Manufacturer registration numbers as foreseen in:

Annex A dated 2022-11-09

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the medical devices fulfill the applicable requirements of Directive 93/42/EEC. In compliance with German law, a safety officer has been appointed for Germany.

2022-11-09

Dr. Philipp Hohenbrink
Director AR Services
MDSS GmbH

Digitally signed by Jighili Tatiana
Date: 2023.10.16 10:41:43 EEST
Reason: MoldSign Signature
Location: Moldova

Annex A dated 2022-11-09
Manufacturer: Ares Medikal San. Tic. Ltd. Sti

UMDNS / GMDN Code Description Notified Medical Device Product Name & Catalogue Number	GMDN Code	Risk Class	Cat. Code	Registration Number	NB No. / NB Certificate No.	NB Cert. Valid Until YYYY-MM-DD
Pressure bandage, non-latex, single-use	**10284**	**Is**	**10**	**DE/CA09/00158054**	**0068/0068/QCO-DM/066-2018**	**2023-10-14**
Angio Closure Pad						
ACP7000 Angio-Closure Pad						
Angiographic syringe	**15286**	**IIa**	**10**	**DE/CA09/00158055**	**0068/0068/QCO-DM/065-2018**	**2023-10-14**
Angiographic Syringe						
AS8000 Angiographic Syringe						
AS8001 Angiographic Syringe						
AS8002 Angiographic Syringe						
AS8003 Angiographic Syringe						
AS8004 Angiographic Syringe						
AS8005 Angiographic Syringe						
AS8006 Angiographic Syringe						
AS8007 Angiographic Syringe						
AS8008 Angiographic Syringe						
AS8009 Angiographic Syringe						
AS8010 Angiographic Syringe						
Catheter/overtube balloon inflator, single-use	**17541**	**Is**	**10**	**DE/CA09/00158056**	**0068/0068/QCO-DM/066-2018**	**2023-10-14**
Balloon Inflation Device						
BID6000 Balloon Inflation Device						
BID6001 Balloon Inflation Device						
BID6002 Balloon Inflation Device						
BID6003 Balloon Inflation Device						
BID6004 Balloon Inflation Device						
BID6005 Balloon Inflation Device						

TAH

Annex A dated 2022-11-09
Manufacturer: Ares Medikal San. Tic. Ltd. Sti

UMDNS / GMDN Code Description Notified Medical Device Product Name & Catalogue Number	GMDN Code	Risk Class	Cat. Code	Registration Number	NB No. / NB Certificate No.	NB Cert. Valid Until YYYY-MM-DD
Intravenous administration tubing extension set	**12170**	**IIa**	**10**	**DE/CA09/00158057**	**0068/0068/QCO-DM/065-2018**	**2023-10-14**
Connecting Tubing						
CT1101 Connecting Tubing						
CT1102 Connecting Tubing						
CT1103 Connecting Tubing						
CT1104 Connecting Tubing						
CT1105 Connecting Tubing						
CT1106 Connecting Tubing						
CT1107 Connecting Tubing						
CT1108 Connecting Tubing						
CT1201 Connecting Tubing						
CT1202 Connecting Tubing						
CT1203 Connecting Tubing						
CT1204 Connecting Tubing						
CT1205 Connecting Tubing						
CT1206 Connecting Tubing						
CT1207 Connecting Tubing						
CT1208 Connecting Tubing						
CT1209 Connecting Tubing						
Peripheral vascular guidewire, manual	**58115**	**IIa**	**10**	**DE/CA09/00158058**	**0068/0068/QCO-DM/065-2018**	**2023-10-14**
Guidewire						
GW2101 Guide Wires						
GW2102 Guide Wires						
GW2103 Guide Wires						
GW2104 Guide Wires						
GW2105 Guide Wires						
GW2106 Guide Wires						
GW2107 Guide Wires						

TAH

Annex A dated 2022-11-09
Manufacturer: Ares Medikal San. Tic. Ltd. Sti

UMDNS / GMDN Code Description Notified Medical Device Product Name & Catalogue Number	GMDN Code	Risk Class	Cat. Code	Registration Number	NB No. / NB Certificate No.	NB Cert. Valid Until YYYY-MM-DD
GW2108 Guide Wires						
GW2109 Guide Wires						
GW2201 Guide Wires						
GW2202 Guide Wires						
GW2203 Guide Wires						
GW2204 Guide Wires						
GW2205 Guide Wires						
GW2206 Guide Wires						
GW2207 Guide Wires						
GW2208 Guide Wires						
GW2209 Guide Wires						
Double-lumen haemodialysis catheter, implantable	**37278**	**IIa**	**10**	**DE/CA09/00158059**	**0068/0068/QCO-DM/065-2018**	**2023-10-14**
Hemodialysis Catheter Kits						
HCT10001 Hemodialysis Catheter Kits						
HCT10002 Hemodialysis Catheter Kits						
HCT10003 Hemodialysis Catheter Kits						
HCT10004 Hemodialysis Catheter Kits						
HCT10005 Hemodialysis Catheter Kits						
HCT10006 Hemodialysis Catheter Kits						
HCT10007 Hemodialysis Catheter Kits						
HCT10008 Hemodialysis Catheter Kits						
HCT10009 Hemodialysis Catheter Kits						
HCT10010 Hemodialysis Catheter Kits						
HCT10011 Hemodialysis Catheter Kits						
HCT10012 Hemodialysis Catheter Kits						
HCT10013 Hemodialysis Catheter Kits						
HCT10014 Hemodialysis Catheter Kits						
HCT10015 Hemodialysis Catheter Kits						
HCT10016 Hemodialysis Catheter Kits						

TAH

Annex A dated 2022-11-09
Manufacturer: Ares Medikal San. Tic. Ltd. Sti

UMDNS / GMDN Code Description Notified Medical Device Product Name & Catalogue Number	GMDN Code	Risk Class	Cat. Code	Registration Number	NB No. / NB Certificate No.	NB Cert. Valid Until YYYY-MM-DD
HCT10017 Hemodialysis Catheter Kits						
HCT10018 Hemodialysis Catheter Kits						
HCT10019 Hemodialysis Catheter Kits						
HCT10020 Hemodialysis Catheter Kits						
HCT10021 Hemodialysis Catheter Kits						
HCT10022 Hemodialysis Catheter Kits						
HCT10023 Hemodialysis Catheter Kits						
HCT10024 Hemodialysis Catheter Kits						
HCT10025 Hemodialysis Catheter Kits						
HCT10026 Hemodialysis Catheter Kits						
HCT10027 Hemodialysis Catheter Kits						
HCT10028 Hemodialysis Catheter Kits						
HCT10029 Hemodialysis Catheter Kits						
HCT10030 Hemodialysis Catheter Kits						
HCT10031 Hemodialysis Catheter Kits						
HCT10032 Hemodialysis Catheter Kits						
HCT10033 Hemodialysis Catheter Kits						
HCT10034 Hemodialysis Catheter Kits						
HCT10035 Hemodialysis Catheter Kits						
HCT10036 Hemodialysis Catheter Kits						
HCT10037 Hemodialysis Catheter Kits						
HCT10038 Hemodialysis Catheter Kits						
HCT10039 Hemodialysis Catheter Kits						
HCT10040 Hemodialysis Catheter Kits						
HCT10041 Hemodialysis Catheter Kits						
HCT10042 Hemodialysis Catheter Kits						
HCT10043 Hemodialysis Catheter Kits						
HCT10044 Hemodialysis Catheter Kits						
HCT10045 Hemodialysis Catheter Kits						
HCT10046 Hemodialysis Catheter Kits						

TAH

Annex A dated 2022-11-09
Manufacturer: Ares Medikal San. Tic. Ltd. Sti

UMDNS / GMDN Code Description Notified Medical Device Product Name & Catalogue Number	GMDN Code	Risk Class	Cat. Code	Registration Number	NB No. / NB Certificate No.	NB Cert. Valid Until YYYY-MM-DD
HCT10047 Hemodialysis Catheter Kits						
HCT10048 Hemodialysis Catheter Kits						
HCT10049 Hemodialysis Catheter Kits						
HCT10050 Hemodialysis Catheter Kits						
HCT10051 Hemodialysis Catheter Kits						
HCT10052 Hemodialysis Catheter Kits						
HCT10053 Hemodialysis Catheter Kits						
HCT10054 Hemodialysis Catheter Kits						
HCT10055 Hemodialysis Catheter Kits						
HCT10056 Hemodialysis Catheter Kits						
HCT10057 Hemodialysis Catheter Kits						
HCT10058 Hemodialysis Catheter Kits						
HCT10059 Hemodialysis Catheter Kits						
HCT10060 Hemodialysis Catheter Kits						
HCT10061 Hemodialysis Catheter Kits						
HCT10062 Hemodialysis Catheter Kits						
HCT10063 Hemodialysis Catheter Kits						
HCT10064 Hemodialysis Catheter Kits						
HCT10065 Hemodialysis Catheter Kits						
HCT10066 Hemodialysis Catheter Kits						
HCT10067 Hemodialysis Catheter Kits						
HCT10068 Hemodialysis Catheter Kits						
HCT10069 Hemodialysis Catheter Kits						
HCT10070 Hemodialysis Catheter Kits						
HCT10071 Hemodialysis Catheter Kits						
HCT10072 Hemodialysis Catheter Kits						
HCT10073 Hemodialysis Catheter Kits						
HCT10074 Hemodialysis Catheter Kits						
HCT10075 Hemodialysis Catheter Kits						
HCT10076 Hemodialysis Catheter Kits						

TAH

Annex A dated 2022-11-09
Manufacturer: Ares Medikal San. Tic. Ltd. Sti

UMDNS / GMDN Code Description Notified Medical Device Product Name & Catalogue Number	GMDN Code	Risk Class	Cat. Code	Registration Number	NB No. / NB Certificate No.	NB Cert. Valid Until YYYY-MM-DD
HCT10077 Hemodialysis Catheter Kits						
HCT10078 Hemodialysis Catheter Kits						
HCT10079 Hemodialysis Catheter Kits						
HCT10080 Hemodialysis Catheter Kits						
HCT10081 Hemodialysis Catheter Kits						
HCT10082 Hemodialysis Catheter Kits						
HCT10083 Hemodialysis Catheter Kits						
HCT10084 Hemodialysis Catheter Kits						
HCT10085 Hemodialysis Catheter Kits						
HCT10086 Hemodialysis Catheter Kits						
HCT10087 Hemodialysis Catheter Kits						
HCT10088 Hemodialysis Catheter Kits						
HCT10089 Hemodialysis Catheter Kits						
HCT10090 Hemodialysis Catheter Kits						
HCT10091 Hemodialysis Catheter Kits						
HCT10092 Hemodialysis Catheter Kits						
HCT10093 Hemodialysis Catheter Kits						
HCT10094 Hemodialysis Catheter Kits						
HCT10095 Hemodialysis Catheter Kits						
HCT10096 Hemodialysis Catheter Kits						
HCT10097 Hemodialysis Catheter Kits						
HCT10098 Hemodialysis Catheter Kits						
HCT10099 Hemodialysis Catheter Kits						
HCT10100 Hemodialysis Catheter Kits						

TAH

Annex A dated 2022-11-09
Manufacturer: Ares Medikal San. Tic. Ltd. Sti

UMDNS / GMDN Code Description Notified Medical Device Product Name & Catalogue Number	GMDN Code	Risk Class	Cat. Code	Registration Number	NB No. / NB Certificate No.	NB Cert. Valid Until YYYY-MM-DD
Angioplasty catheter connector	**36177**	**IIa**	**10**	**DE/CA09/00158060**	**0068/0068/QCO-DM/065-2018**	**2023-10-14**
Hemostasis Valve Set						
HVS3000 Hemostatis Valve Set HVS3001 Hemostatis Valve Set HVS3002 Hemostatis Valve Set HVS3003 Hemostatis Valve Set HVS3004 Hemostatis Valve Set						
Intra-arterial needle	**12747**	**IIa**	**10**	**DE/CA09/00158061**	**0068/0068/QCO-DM/065-2018**	**2023-10-14**
Introducer Needle						
IN4000 Introducer Needle IN4001 Introducer Needle IN4002 Introducer Needle						
Catheters, introducer	**58865**	**IIa**	**10**	**DE/CA09/00158062**	**0068/0068/QCO-DM/065-2018**	**2023-10-14**
Introducer Set						
IS9000 Introducer Sets IS9001 Introducer Sets IS9002 Introducer Sets IS9003 Introducer Sets IS9004 Introducer Sets IS9005 Introducer Sets IS9006 Introducer Sets IS9007 Introducer Sets IS9008 Introducer Sets IS9009 Introducer Sets						

TAH

Annex A dated 2022-11-09
Manufacturer: Ares Medikal San. Tic. Ltd. Sti

UMDNS / GMDN Code Description Notified Medical Device Product Name & Catalogue Number	GMDN Code	Risk Class	Cat. Code	Registration Number	NB No. / NB Certificate No.	NB Cert. Valid Until YYYY-MM-DD
IS9010 Introducer Sets IS9011 Introducer Sets IS9012 Introducer Sets IS9013 Introducer Sets IS9014 Introducer Sets IS9015 Introducer Sets IS9016 Introducer Sets IS9017 Introducer Sets						
Intravenous line stopcock	**32172**	**Is**	**10**	**DE/CA09/00158063**	**0068/0068/QCO-DM/066-2018**	**2023-10-14**
Manifold						
M5000 Manifold M5001 Manifold M5002 Manifold M5003 Manifold						

TAH

CE 0068

ISO 13485 : 2016

EC DECLARATION OF CONFORMITY

Manufacturer: Ares Medikal San. Tic. Ltd. Şti.
5821/1 SK. NO:6 ASIK VEYSEL MH. KARABAGLAR,
35110 - IZMIR, TURKEY
PHONE: (+90) 232 264 70 00
FAX : (+90) 232 264 90 00

Product: Balloon Inflation Device

GMDN : 17540

Brand: ARES

Reference Number : BID6001, BID6002, BID6003, BID6004, BID6005

Applied standards:
EN ISO 13485: 2012, EN ISO 14971: 2012, EN 1041:2008, EN ISO 15223-1:2016, EN ISO 10555-1:2009, EN ISO 11070:2014, EN 10993-1: 2011, EN 10993-4:2010, EN 10993-5: 2010, EN ISO 10993-7:2010, EN 10993-10:2010, EN ISO 10993-10:2002+A1:2006, EN ISO 10993-11:2010, EN ISO 11135:2014, EN ISO 11737-1: 2006, EN 11737-2: 2009, EN ISO 11607-1:2009, EN ISO 11607-2:2006

Classification : Medical Device Directive 93/42/EEC Rule 1 of Annex IX
Class Is

Conformity assessment Route
Medical Device Directive 93/42/EEC including amendment 2007/47/EC Annex II
We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices including amendment 2007/47/EC all supporting documentation is retained under the premises of the manufacturer. we declare that our products do not contain human blood derivatives, tissues of animal origin and any medicinal products.
Notified body : MTIC InterCert S.r.l. via Moscova 11,20123 Milano (MI), Italy
Phone : +39 02 97071800 Fax : +39 02 9308176
Place and Date of Issue: Izmır, Turkey / 15.10.2018
Signature : SERHAT ÇELİK Chief Executive Officer

ARES MEDİKAL
SANAYİ TİCARET LTD. ŞTİ.
Fabrika : Aşık Veysel Mah. 5821/1 Sk. No:6
Factory Karabağlar - İZMİR
Tel : +90 232 264 70 00 Fax : +90 232 264 90 00
Gaziemir Vergi Dairesi 074 038 0394
Tic. Sic. No : 113178 Mersis No:4545336122779750

ARES MEDİKAL SANAYİ TİCARET LTD. ŞTİ.
Aşık Veysel Mah. 5821/1 Sk. No:6 Karabağlar - İZMİR / TÜRKİYE
Tel: +90 232 264 70 00 **Fax:** +90 232 264 90 00
E-mail: info@ares-medikal.com **Web:** www.ares-medikal.com
Gaziemir V.D. 074 038 0394
Tic. Sic. No: 113178
Mersis No: 4545336122779750
Firma Tanımlayıcı No: 2667269009591
HALK BANKASI - Gaziemir Şb. - IBAN No: TR30 0001 2009 7460 0010 2603 77 • **ZİRAAT BANKASI** - Ege Tıp Şb. - IBAN No: TR10 0001 0014 4647 0931 6650 03

CE 0068

ISO 13485 : 2016

EC DECLARATION OF CONFORMITY

Manufacturer: Ares Medikal San. Tic. Ltd. Şti.
5821/1 SK. NO:6 ASIK VEYSEL MH. KARABAGLAR,
35110 - IZMIR, TURKEY
PHONE: (+90) 232 264 70 00
FAX : (+90) 232 264 90 00

Product: Hemostasis Valve Set

GMDN : 36177

Brand: ARES

Reference Number : HVS3000, HVS3001, HVS3002, HVS3003, HVS3004

Applied standards:
EN ISO 13485: 2012, EN ISO 14971: 2012, EN 1041:2008, EN ISO 15223-1:2016, EN ISO 10555-1:2009, EN ISO 11070:2014, EN 10993-1: 2011, EN 10993-4:2010, EN 10993-5: 2010, EN ISO 10993-7:2010, EN 10993-10:2010, EN ISO 10993-10:2002+A1:2006, EN ISO 10993-11:2010, EN ISO 11135:2014, EN ISO 11737-1: 2006, EN 11737-2: 2009, EN ISO 11607-1:2009, EN ISO 11607-2:2006

Classification : Medical Device Directive 93/42/EEC Rule 1 of Annex IX
Class IIa

Conformity assessment Route
Medical Device Directive 93/42/EEC including amendment 2007/47/EC Annex II
We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices including amendment 2007/47/EC all supporting documentation is retained under the premises of the manufacturer. we declare that our products do not contain human blood derivatives, tissues of animal origin and any medicinal products.
Notified body : MTIC InterCert S.r.l. via Moscova 11,20123 Milano (MI), Italy
Phone : +39 02 97071800 Fax : +39 02 9308176
Email : info@mticert.org Website : www.mticert.org

Place, Date of Issue: Izmir, Turkey, 07.01.2021
Signature : SERHAT ÇELİK Chief Executive Officer

ARES MEDİKAL SANAYİ TİCARET LTD. ŞTİ.
Fabrika : Aşık Veysel Mah. 5821/1 Sk. No:6
Factory Karabağlar - İZMİR
Tel : +90 232 264 70 00 Fax : +90 232 264 90 00
Gaziemir Vergi Dairesi 074 038 0394
Tic. Sic. No : 113178 Mersis No:4545336122779750

ARES MEDİKAL SANAYİ TİCARET LTD. ŞTİ.
Aşık Veysel Mah. 5821/1 Sk. No:6 Karabağlar - İZMİR / TÜRKİYE
Tel: +90 232 264 70 00 **Fax:** +90 232 264 90 00
E-mail: info@ares-medikal.com **Web:** www.ares-medikal.com
Gaziemir V.D. 074 038 0394
Tic. Sic. No: 113178
Mersis No: 4545336122779750
Firma Tanımlayıcı No: 2667269009591
HALK BANKASI - Gaziemir Şb. - IBAN No: TR30 0001 2009 7460 0010 2603 77 • **ZİRAAT BANKASI** - Ege Tıp Şb. - IBAN No: TR10 0001 0014 4647 0931 6650 03

CE 0068

ISO 13485 : 2016

EC DECLARATION OF CONFORMITY

Manufacturer : Ares Medikal San. Tic. Ltd. Şti.
5821/1 SK. NO:6 ASIK VEYSEL MH. KARABAGLAR,
35110 - IZMIR, TURKEY
PHONE: (+90) 232 264 70 00
FAX : (+90) 232 264 90 00

Product : Introducer Set (Femoral)

Ref Code: IS9000, IS9001, IS9002, IS9003, IS9004, IS9005, IS9006, IS9007, IS9008, IS9009, IS9010, IS9011

Set Contents: Introducer Sheath, Dilator, Mini Guidewire, Syringe, Scalpel, Needle

Classification: Medical Device Directive 93/42/EEC Rule 6 of Annex IX Class IIa

Applied standards:
EN ISO 13485: 2012, EN ISO 14971: 2012, EN 1041:2008, EN ISO 15223-1:2016, EN ISO 10555-1:2009, EN ISO 11070:2014, EN 10993-1: 2011, EN 10993-4:2010, EN 10993-5: 2010, EN ISO 10993-7:2010, EN 10993-10:2010, EN ISO 10993-10:2002+A1:2006, EN ISO 10993-11:2010, EN ISO 11135:2014, EN ISO 11737-1: 2006, EN 11737-2: 2009, EN ISO 11607-1:2009, EN ISO 11607-2:2006

Conformity assessment Route
Medical Device Directive 93/42/EEC including amendment 2007/47/EC Annex II
We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices including amendment 2007/47/EC all supporting documentation is retained under the premises of the manufacturer. we declare that our products do not contain human blood derivatives, tissues of animal origin and any medicinal products.

Notified body : MTIC InterCert S.r.l. via Moscova 11,20123 Milano (MI), Italy
Phone : +39 02 97071800 Fax : +39 02 9308176
Email : info@mticert.org Website : www.mticert.org
Notified Body number : 0068

Place, Date of Issue: Izmir, Turkey,27.02.2021
Signature : SERHAT ÇELİK Chief Executive Officer

ARES MEDİKAL
SANAYİ TİCARET LTD. ŞTİ.
Fabrika : Aşık Veysel Mah. 5821/1 Sk. No:6
Factory Karabağlar - İZMİR
Tel : +90 232 264 70 00 Fax : +90 232 264 90 00
Gaziemir Vergi Dairesi 074 038 0394
Tic. Sic. No : 113178 Mersis No:4545336122779750

ARES MEDİKAL SANAYİ TİCARET LTD. ŞTİ.
Aşık Veysel Mah. 5821/1 Sk. No:6 Karabağlar - İZMİR / TÜRKİYE
Tel: +90 232 264 70 00 **Fax:** +90 232 264 90 00
E-mail: info@ares-medikal.com **Web:** www.ares-medikal.com
Gaziemir V.D. 074 038 0394
Tic. Sic. No: 113178
Mersis No: 4545336122779750
Firma Tanımlayıcı No: 2667269009591
HALK BANKASI - Gaziemir Şb. - IBAN No: TR30 0001 2009 7460 0010 2603 77 • **ZİRAAT BANKASI** - Ege Tıp Şb. - IBAN No: TR10 0001 0014 4647 0931 6650 03

CE 0068

ISO 13485 : 2016

EC DECLARATION OF CONFORMITY

Manufacturer : Ares Medikal San. Tic. Ltd. Şti.
5821/1 SK. NO:6 ASIK VEYSEL MH. KARABAGLAR,
35110 - IZMIR, TURKEY
PHONE: (+90) 232 264 70 00
FAX : (+90) 232 264 90 00

Product : Introducer Set (Radial)

Ref Code: IS9012, IS9013, IS9014 IS9015, IS9016, IS9017

Set Contents: Introducer Sheath, Dilator, Mini Guidewire, Scalpel, Needle

Classification: Medical Device Directive 93/42/EEC Rule 6 of Annex IX Class IIa

Applied standards:
EN ISO 13485: 2012, EN ISO 14971: 2012, EN 1041:2008, EN ISO 15223-1:2016, EN ISO 10555-1:2009, EN ISO 11070:2014, EN 10993-1: 2011, EN 10993-4:2010, EN 10993-5: 2010, EN ISO 10993-7:2010, EN 10993-10:2010, EN ISO 10993-10:2002+A1:2006, EN ISO 10993-11:2010, EN ISO 11135:2014, EN ISO 11737-1: 2006, EN 11737-2: 2009, EN ISO 11607-1:2009, EN ISO 11607-2:2006

Conformity assessment Route
Medical Device Directive 93/42/EEC including amendment 2007/47/EC Annex II
We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices including amendment 2007/47/EC all supporting documentation is retained under the premises of the manufacturer. we declare that our products do not contain human blood derivatives, tissues of animal origin and any medicinal products.

Notified body : MTIC InterCert S.r.l. via Moscova 11,20123 Milano (MI), Italy
Phone : +39 02 97071800 Fax : +39 02 9308176
Email : info@mticert.org Website : www.mticert.org
Notified Body number : 0068

Place, Date of Issue: Izmir, Turkey,27.02.2021
Signature : SERHAT ÇELİK Chief Executive Officer

ARES MEDİKAL
SANAYİ TİCARET LTD. ŞTİ.
Fabrika : Aşık Veysel Mah. 5821/1 Sk. No:6
Factory Karabağlar - İZMİR
Tel : +90 232 264 70 00 Fax : +90 232 264 90 00
Gaziemir Vergi Dairesi 074 038 0394
Tic. Sic. No : 113178 Mersis No:4545336122779750

ARES MEDİKAL SANAYİ TİCARET LTD. ŞTİ.
Aşık Veysel Mah. 5821/1 Sk. No:6 Karabağlar - İZMİR / TÜRKİYE
Tel: +90 232 264 70 00 **Fax:** +90 232 264 90 00
E-mail: info@ares-medikal.com **Web:** www.ares-medikal.com
Gaziemir V.D. 074 038 0394
Tic. Sic. No: 113178
Mersis No: 4545336122779750
Firma Tanımlayıcı No: 2667269009591
HALK BANKASI - Gaziemir Şb. - IBAN No: TR30 0001 2009 7460 0010 2603 77 • **ZİRAAT BANKASI** - Ege Tıp Şb. - IBAN No: TR10 0001 0014 4647 0931 6650 03

CE 0068

ISO 13485 : 2016

LETTER OF AUTHORIZATION

Date: September,26. 2023

To Whom It May Concern:

Hereby, we

Company Name :Ares Medikal Sanayi Ticaret Ltd. Şti.

Address : 6094 Sk No:6 Egemenlik Mh. Bornova İzmir - TURKEY

Phone number : 232 264 70 00

Certify that:

Triumf Motiv SRL

Address: Republic Of Moldova, MD 2043-str. Grenoble 193, et.13, of.1

Phone number: (+373 22) 76 84 62, 76 88 41

Triumf-Motiv SRL is our authorized representative and distributor on the territory of the Republic of Moldova.

We allow this company to register our products with the competent authorities on the territory of the Republic of Moldova, as well as to promote, sell, distribute our products in the Republic of Moldova, and we will provide all necessary assistance to expand the market of medical supplies and devices of our brand ARES & CARDIOHEALTH in your country.

This letter of authorization remains valid for five years, starting from September, 2023and expiring on March 09, 2028.

Name : SERHAT ÇELİK

Title : GENERAL MANAGER

Signature:

ARES MEDİKAL
SANAYİ TİCARET LTD. ŞTİ.
Fabrika : Aşık Veysel Mah. 5821/1 Sk. No:6
Factory Karabağlar - İZMİR
Tel : +90 232 264 70 00 Fax : +90 232 264 90 00
Gaziemir Vergi Dairesi 074 038 0394
Tic. Sic. No : 113178 Mersis No:0454336122779750

CERTIFICATE

ARES MEDİKAL SAN. TİC. LTD. ŞTİ.

CENTRAL ADDRESS: AŞIK VEYSEL MAH. 5821/1 SOK.NO:6 KARABAĞLAR / İZMİR / TÜRKİYE
BRANCH ADDRESS: EGEMENLİK MAH. 6094 SOK. NO:6 35070 BORNOVA / İZMİR / TÜRKİYE

Has been assessed and found to Comply with the Requirements of:

ISO 13485:2016

Medical Devices-Quality Management System is applicable to:

MANUFACTURE, STERILIZATION AND SALES OF INTRODUCER SETS, INTRODUCER NEEDLE, GUIDEWIRES, MANIFOLDS, HEMOSTASIS VALVE SETS, BALLOON INFLATION DEVICES, HEMODIALYSIS CATHETER KITS, CONNECTING TUBING, ANGIO CLOSURE PADS, ANGIOGRAPHIC SYRINGES, ANGIOGRAPHY CATHETERS, GUIDING CATHETERS, ANGIO DRAPE SETS

Certificate Number: 2023/MDQMS/11087 **Initial Certification Date: 21.06.2023**

Certification Period: 3 Years **Certificate Validity Date: 20.06.2024**

IAS ACCREDITED Management Systems Certification Body MSCB-135

IQR Sertifikasyon Onayı

IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.
Beşevler Mah. Kocayunus Sk. No:3 Arslan Han Plaza K:2 Nilüfer / BURSA
Tel.: +90.224.266 00 16 Faks: +90.224.249 41 13 www.iqrcert.com e-posta: info@iqrcert.com