



# EC CERTIFICATE

## Full Quality Assurance System

### Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

M.2016.106.6908-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name : TMT Tibbi Medikal Malzemeleri Sanayi ve Ticaret A.Ş.  
Company Address : Fatih Mah.1188 Sk. No14 PK 35414 Sarıncı, Gazimir İZMİR / TURKEY  
Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)  
Product : 1- Spinal Anesthesia Needles - Sets - Kits - Class III - Sterile  
- Spinal Anesthesia Needles  
- Spinal Anesthesia Sets  
- Combined Spinal Epidural Anesthesia Sets  
- Combined Spinal Epidural Anesthesia Kits  
2- Epidural Anesthesia Needles - Sets - Kits - Class IIa - Sterile  
- Epidural Anesthesia Needles  
- Epidural Anesthesia Sets  
- Epidural Anesthesia Kits  
- Echogenic Transforaminal Epidural Cannula with Blunt Tip  
- Echogenic Transforaminal Epidural Cannula with Blunt Tip Sets  
- Caudal Anesthesia Needles  
- Caudal Anesthesia Sets  
3- Intrauterine Contraceptive Device - Class III - Sterile  
4- Seldinger (Angiography) Needle - Class III - Sterile  
5- Biopsy and Aspiration Needles-Kits and Accessories - Class IIa - Sterile  
6- Medical Accessories for Anesthesia - Class IIa - Sterile  
7- Medical Accessories for Anesthesia-Class I - Sterile

GMDN : 35212, 34845, 58293, 34842, 45178, 34841, 46920, 12747, 47540, 35886, 46350, 45018, 45316, 31245, 18069, 35795, 34916, 37040, 46115

Product Types are attached.

Certificate Number : M.2016.106.6908  
Report Number : MD.3193.YB  
Initial Assessment Date : 16.07.2016  
Registration Date : 28.07.2016  
Recertification Assessment Date : 01.08.2019  
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Expiry Date : 27.05.2024



UDEM International Certification  
Auditing Training Centre Industry  
and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned

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<b>Spinal Anesthesia Needles – Sets – Kits – Class III – Sterile</b>	
<b>Spinal Anesthesia Needles</b>	<b>GMDN: 35212</b>
Quincke Type Spinal Anesthesia Needles	
Quincke Type Spinal Anesthesia Needles – with Guide	
Quincke Type Spinal Anesthesia Needles – with Filtered Aspiration Cannula	
Quincke Type Spinal Anesthesia Needles – with Guide and Filtered Aspiration Cannula	
Atraumatic-Pencil Point Spinal Anesthesia Needles	
Atraumatic-Pencil Point Spinal Anesthesia Needles – with Guide	
Atraumatic-Pencil Point Spinal Anesthesia Needles – with Filtered Aspiration Cannula	
Atraumatic-Pencil Point Spinal Anesthesia Needles – with Guide and Filtered Aspiration Cannula	
Specially Grinded – Curved Type Atraumatic Spinal Anesthesia Needles	
Specially Grinded – Curved Type Atraumatic Spinal Anesthesia Needles – with Guide	
Specially Grinded – Curved Type Atraumatic Spinal Anesthesia Needles – with Filtered Aspiration Cannula	
Specially Grinded – Curved Type Atraumatic Spinal Anesthesia Needles – with Guide and Filtered Aspiration Cannula	
<b>Spinal Anesthesia Sets</b>	<b>GMDN: 34845</b>
Spinal Anesthesia Set with Quincke Type Spinal Anesthesia Needle: (Spinal Needle, Guide Needle (Optional), Filtered Aspiration Cannula, 3 ml – 5 ml Syringe, Transparent Adhesive Surgical Drape, Medical Hydrophilic Swab, Sterile Surgical Towel, Sponge, Hypodermic Needle, Waste Needle Box, Square Plaster)	
Spinal Anesthesia Set with Atraumatic Type (Pencil Point) Spinal Anesthesia Needle: (Spinal Needle, Guide Needle (Optional), Filtered Aspiration Cannula, 3 ml – 5 ml Syringe, Transparent Adhesive Surgical Drape, Medical Hydrophilic Swab, Sterile Surgical Towel, Sponge, Hypodermic Needle, Waste Needle Box, Square Plaster)	
Spinal Anesthesia Set with Specially Grinded – Curved Type Atraumatic Spinal Anesthesia Needle: (Spinal Needle, Guide Needle (Optional), Filtered Aspiration Cannula, 3 ml – 5 ml Syringe, Transparent Adhesive Surgical Drape, Medical Hydrophilic Swab, Sterile Surgical Towel, Sponge, Hypodermic Needle, Waste Needle Box, Square Plaster)	
<b>Combined Spinal Epidural Anesthesia Sets</b>	<b>GMDN: 34845</b>
Combined Spinal Epidural Anesthesia Set: (Spinal Needle with Combined Application Fixator, Epidural Needle, Epidural Catheter, Epidural LOR Syringe / Automatic LOR Syringe, Epidural Filter, Filtered Aspiration Cannula, Epidural Catheter Fixing Device, Epidural Filter Fixing Device, Catheter Connector(Tuohy Borst Connector), Yellow identification label)	
Single Shot Combined Spinal Epidural Anesthesia Set: (Spinal Needle with Combined Application Fixator, Epidural LOR Syringe / Automatic LOR Syringe, Epidural Needle, Filtered Aspiration Cannula)	
<b>Combined Spinal Epidural Anesthesia Kits</b>	<b>GMDN: 34845</b>
Combined Spinal Epidural Anesthesia Kit: (Spinal Needle with Combined Application Fixator, Epidural Needle, Epidural Catheter, Epidural Filter, Epidural LOR Syringe / Automatic LOR Syringe, Catheter Connector(Tuohy Borst Connector), Epidural Catheter Fixing Device, Epidural Filter Fixing Device, Filtered Aspiration Cannula, Hypodermic Needle, 3 ml – 5 ml Inejctor, Transparent Adhesive Surgical Drape, Medical Hydrophilic Swab, Sterile Surgical Towel, Plaster, Sponge, Waste Needle Box, Yellow Identification Label)	
<b>Epidural Anesthesia Needles – Sets – Kits – Class IIa – Sterile</b>	
<b>Epidural Anesthesia Needles</b>	<b>GMDN: 58293</b>
<b>Epidural Anesthesia Sets</b>	<b>GMDN: 34842</b>
Epidural Anesthesia Set: (Epidural Needle, Epidural Catheter, Epidural Filter, Epidural LOR Syringe / Automatic LOR Syringe, Catheter Connector(Tuohy Borst Connector), Epidural Catheter Fixing Device, Epidural Filter Fixing Device, Yellow Identification Label)	
Epidural Anesthesia Set (Mini A): (Epidural Needle, Epidural Catheter, Epidural Filter, Catheter Connector(Tuohy Borst Connector), Epidural Catheter Fixing Device, Yellow Identification Label)	
Epidural Anesthesia Set (Mini B): (Epidural Catheter, Epidural Filter, Catheter Connector(Tuohy Borst Connector), Epidural Catheter Fixing Device, Epidural Filter Fixing Device, Yellow Identification Label)	
Epidural Anesthesia Set (Mini C): (Epidural Needle, Epidural Catheter, Catheter Connector(Tuohy Borst Connector), Epidural Catheter Fixing Device)	



This document containing 2 (two) pages is the Annex of the Certificate with the revision number 01, with the number M.2016.106.6908 and with the registration date of 28.07.2016 and with the re-issue date 18.05.2021 issued for "TMT Tibbi Medikal Malzemeleri Sanayi ve Ticaret A.Ş." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive.

<b>Epidural Anesthesia Kits</b>	<b>GMDN: 34842</b>
Epidural Anesthesia Kits: (Epidural Needle, Epidural Catheter, Epidural Filter, Epidural LOR Syringe / Automatic LOR Syringe, Catheter Connector(Tuohy Borst Connector), Epidural Catheter Fixing Device, Epidural Filter Fixing Device, Hypodermic Needle, 3 ml – 5 ml Syringe, Transparent Adhesive Surgical Drape, Medical Hydrophilic Swab, Sterile Surgical Towel, Plaster, Sponge, Waste Needle Box, Yellow Identification Label)	
<b>Echogenic Transforaminal Epidural Cannula with Blunt Tip</b>	<b>GMDN: 45178</b>
<b>Echogenic Transforaminal Epidural Cannula with Blunt Tip Sets</b>	<b>GMDN: 45178</b>
Echogenic Transforaminal Epidural Cannula with Blunt Tip Set: (Echogenic Transforaminal Epidural Cannula with Blunt Tip Needle, IV Cannula(Branül), 3 ml – 5 ml Syringe, Guide Needle, Filtered Aspiration Cannula, Sponge, Medical Hydrophilic Swab, Hypodermic Needle, Waste Needle Box, Pressure Extension Line, Transparent Adhesive Surgical Drape, Sterile Surgical Towel)	
<b>Caudal Anesthesia Needle</b>	<b>GMDN: 34841</b>
<b>Caudal Anesthesia Needle – with Filtered Aspiration Cannula</b>	<b>GMDN: 34841</b>
<b>Caudal Anesthesia Sets</b>	<b>GMDN: 34841</b>
Caudal Anesthesia Set: (Caudal Needle, Filtered Aspiration Cannula, 3 ml – 5 ml Syringe, Transparent Adhesive Surgical Drape, Medical Hydrophilic Swab, Sterile Surgical Towel, Sponge, Waste Needle Box, Hypodermic Needle, Square Plaster)	
<b>Intrauterine Contraceptive Device – Class III – Sterile</b>	<b>GMDN: 46920</b>
<b>Seldinger (Angiography) Needle – Class III – Sterile</b>	<b>GMDN: 12747</b>
<b>Biopsy and Aspiration Needles and Accessories – Class IIa – Sterile</b>	
<b>Fully Automatic Biopsy Needle</b>	<b>GMDN: 47540</b>
<b>Fully Automatic Gun Compatible Biopsy Needle</b>	<b>GMDN: 47540</b>
<b>Manual Guillotine Biopsy Needle</b>	<b>GMDN: 47540</b>
<b>Semi-Automatic Guillotine Biopsy Needle</b>	<b>GMDN: 47540</b>
<b>Sternal Crista Iliac Aspiration Needle</b>	<b>GMDN: 35886</b>
<b>Chiba Needle</b>	<b>GMDN: 35886</b>
<b>Amniocentesis Needle</b>	<b>GMDN: 35886</b>
<b>Cordocentesis Needle</b>	<b>GMDN: 35886</b>
<b>Bone Marrow Biopsy Needle</b>	<b>GMDN: 46350</b>
<b>Bone Marrow Biopsy Kit</b>	<b>GMDN: 46350</b>
Bone Marrow Biopsy Kit Bone Marrow Biopsy Needle, Marrow Collection Cannula/Probe, Marrow Transfer Ring, Pusher Stylet, 10 ml Syringe, Medical Hydrophilic Swab, Sterile Surgical Towel)	
<b>Medical Accessories / Products for Anesthesia - Class IIa - Sterile</b>	
<b>Guide Needle</b>	<b>GMDN: 45018</b>
<b>Filtered Aspiration Cannula</b>	<b>GMDN: 45316</b>
<b>Epidural Filter</b>	<b>GMDN: 31245</b>
<b>Epidural LOR (Loss Of Resistance) Syringe</b>	<b>GMDN: 18069</b>
<b>Epidural Automatic LOR (Loss Of Resistance) Syringe</b>	<b>GMDN: 18069</b>
<b>Epidural Catheter</b>	<b>GMDN: 35795</b>
<b>Medical Accessories / Products for Anesthesia – Class I – Sterile</b>	
<b>Epidural Catheter Fixing Device</b>	<b>GMDN: 34916</b>
<b>Epidural Filter Fixing Device</b>	<b>GMDN: 37040</b>
<b>Catheter Connector(Tuohy Borst Connector)</b>	<b>GMDN: 46115</b>