TÜRK STANDARDLARI ENSTİTÜSÜ

TURKISH STANDARDS INSTITUTION

Full Quality Assurance Certificate

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

Notified Body	:	Türk Standardları Enstitüsü (TSE) - Necatibey Cad. No:112 Bakanlıklar Ankara Türkiye (NB 1783)
Company Name	:	ZADİ TIBBİ GEREÇLER SAN. VE TIC. A.Ş.
Company Address	:	Küçükçekmece İkitelli OSB Mah. İmsan B Blok Sok. No: 13 Küçükçekmece / İstanbul Turkey
Manufacturing Site	:	Pharmaplast S.A.E'. Amria Factory, Amria FreeZone, Alexandria, Egypt
Scope	:	INCISION COVER WITH PVP IODINE (STERILE)
GMDN Code	:	58302
Classification Rule	:	Rule 4 and 13, Class III
Inspection Report Number	:	2300-MDD-204/2020-02, 2300-MDD-204/2020-05
First Issue Date	:	20.05.2021
Validity Date	:	26.05.2024

The manufacturer's quality system is inspected in accordance with Annex II of the Medical Device Directive and the quality system meets the requirements of Medical Device Directive Annex II. The Notified Body has the right to carry out the necessary inspections in accordance with Medical Device Directive Annex II Section 5. For Class III products covered by this certificate, a EC Design Examination Certificate issued in accordance with Medical Device Directive Annex II Section 4 is also required.

Certificate No: 1783- MDD-219

Fırat HACIOĞLU

Deputy Director of Directives

ANKARA Rev 00, 20/05/2021

Please check the validity of certificate from TSE's web page "https://basvuruportal.tse.org.tr/Genel/FirmaArama.aspx?ref=en#open"

TÜRK STANDARTLARI ENSTİTÜSÜ DİREKTİFLER MÜDÜRLÜĞÜ 1783 DIRECTORATE OF DIRECTIVE TURKISH STANDARDS INSTITUTION

TÜRK STANDARDLARI ENSTİTÜSÜ

TURKISH STANDARDS INSTITUTION

Full Quality Assurance Certificate Certification History

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

Certificate No: 1783-MDD-219 Rev 00

CERTIFICATE HISTORY		
Date	**Revision Number**	**Reason of Revision**
20.05.2021	Rev 00	-

Full Quality Assurance Certificate Scope Attachment

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

Certificate No: 1783-MDD-219, Rev 00

DIFA Iodine Incision cover with PVP-I	
Reference No	**Size**
Difa 1520 Iodine	15x20 cm
Difa 1528 Iodine	15x28 cm
Difa 3028 Iodine	30x28 cm
Difa 3030 Iodine	30x30 cm
Difa 2845 Iodine	28x45 cm
Difa 3045 Iodine	30x45cm
Difa 4555 Iodine	45x55 cm
Difa 4045 Iodine	40x45 cm
Difa 4245 Iodine	42x45 cm
Difa 3060 Iodine	30x60 cm
Difa 4560 Iodine	45x60 cm
Difa 5080 Iodine	50x80 cm
Difa 9080 Iodine	90x80 cm
Difa 9070 Iodine	90x70 cm
Difa 1014 Iodine FS	10X14 cm
Difa 1010 Iodine FS	10x10 cm
Difa 1015 Iodine FS	10x15 cm
Difa 1020 Iodine FS	10x20 cm
Difa 1025 Iodine FS	10x25 cm
Difa 1030 Iodine FS	10x30 cm
Difa 1520 Iodine FS	15x20 cm
Difa 2030 Iodine FS	20x30 cm

TÜRK STANDARDLARI ENSTİTÜSÜ

TURKISH STANDARDS INSTITUTION

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II (4)

Notified Body	:	Türk Standardları Enstitüsü (TSE) - Necatibey Cad. No:112 Bakanlıklar Ankara Turkey (NB 1783)
Company Name	:	ZADİ TIBBİ GEREÇLER SAN. VE TIC. A.Ş.
Company Address	:	Küçükçekmece İkitelli OSB Mah. İmsan B Blok Sok. No: 13 Küçükçekmece / İstanbul Turkey
Manufacturing Site	:	Pharmaplast S.A.E'. Amria Factory, Amria FreeZone, Alexandria, Egypt
Scope	:	INCISION COVER WITH PVP IODINE (STERILE)
GMDN Code	:	58302
Classification Rule	:	Rule 4 and 13, Class III
Inspection Report Number	:	2300-MDD-204/2020-02, 2300-MDD-204/2020-05
First Issue Date	:	20.05.2021
Validity Date	:	26.05.2024
Full Quality Assurance Certificate Number	:	1783-MDD-219

Above scope has been examined and certified according to the requirements of 93/42 / EC - Medical Device Directive Annex-II Section 4. This certificate is valid with its annexes. It is totally 2 pages, including this page. The products included in the scope mentioned above must also have a certificate of Full Quality Assurance (Annex II excluding Section 4). The Notified Body has the right to carry out the necessary inspections in accordance with Medical Device Directive Annex II Section 5.

Certificate No: 1783- MDD-220

Fırat HACIOĞLU

Deputy Director of Directives

ANKARA Rev 00, 20/05/2021

Please check the validity of certificate from TSE's web page "https://basvuruportal.tse.org.tr/Genel/FirmaArama.aspx?ref=en#open"

TÜRK STANDARTLARI ENSTİTÜSÜ * DIRECTIVE DIREKTİFLER MÜDÜRLÜĞÜ * TURKISH STANDARDS INSTITUTION 1783

TÜRK STANDARDLARI ENSTİTÜSÜ

TURKISH STANDARDS INSTITUTION

EC Design Examination Certificate Annex

Certificate No: 1783-MDD-220, Rev 00

Product Type

CERTIFICATE HISTORY		
Date	**Revision Number**	**Reason of Revision**
20.05.2021	Rev 00	-

DIFA Iodine Incision cover with PVP-I	
Reference No	**Size**
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Difa 1020 Iodine FS	10x20 cm
Difa 1025 Iodine FS	10x25 cm
Difa 1030 Iodine FS	10x30 cm
Difa 1520 Iodine FS	15x20 cm
Difa 2030 Iodine FS	20x30 cm

TÜRK STANDARTLARI ENSTİTÜSÜ * DİREKTİFLER MÜDÜRLÜĞÜ * DIRECTORATE OF DIRECTIVE * TURKISH STANDARDS INSTITUTION * 1783