



TÜRK STANDARLARI ENSTİTÜSÜ
TURKISH STANDARDS INSTITUTION

Full Quality Assurance Certificate

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

Notified Body	: Türk Standartları 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	: WOUND DRESSING WITH CHLORHEXIDINE GLUCONATE (STERILE)
GMDN Code	: 58301
Classification Rule	: Rule 4 and 13, Class III
Inspection Report Number	: 2298-MDD-203/2020-02, 2298-MDD-203/2020-05
First Issue Date	: 08.04.2021
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-207

Fırat HACIOĞLU

Deputy Director of Directives

ANKARA Rev 00, 08/04/2021

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



www.tse.org.tr / Necatibey Cad. No: 112 Bakanlıklar - ANKARA / +90 312 416 62 00

Bu belge hiçbir suretle tahrif edilemez, kısmen veya okunmasını zorlaştıracak şekilde çoğaltılamaz, kazıntı ve silinti yapılamaz.
This certificate cannot be altered, partially duplicated or erased for misunderstanding.



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-207 Rev 00

CERTIFICATE HISTORY		
Date	Revision Number	Reason of Revision
08.04.2021	Rev 00	-

Full Quality Assurance Certificate Scope Attachment

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

Certificate No: 1783-MDD-207, Rev 00

DIFA IV CHG Wound dressing with chlorhexidine gluconate	
Reference No	Size
Difa IV CHG 76	7 cm x 6 cm
Difa IV CHG 77	7 cm x 7 cm
Difa IV CHG 87	8 cm x 7 cm
Difa IV CHG 810	8 cm x 10 cm
Difa IV CHG 2810	8.25 cm x 10 cm
Difa IV CHG 856	8.5 cm x 6 cm
Difa IV CHG 857	8.5 cm x 7 cm
Difa IV CHG 8510	8.5 cm x 10 cm
Difa IV CHG 97	9 cm x 7 cm
Difa IV CHG 910	9 cm x 10 cm
Difa IV CHG 1012	10 cm x 12 cm
Difa IV CHG 1014	10 m x 14 cm
Difa IV CHG 68	6 cm x 8 cm
Difa IV CHG 79	9 cm x 7 cm
Difa IV CHG 85115	8.5 cm x 11.5 cm
Difa IV CHG 5057	5 cm x 5.7 cm
Difa IV CHG 67	6 cm x 7 cm
Difa IV CHG 657 ADV	6.5 cm x 7 cm
Difa IV CHG 79 ADV	7 cm x 9 cm
Difa IV CHG 85115 ADV	8.5 cm x 11.5 cm
Difa IV CHG 1012 ADV	10 cm x 12 cm
Difa IV CHG 10155 ADV	10 cm x 15.5 cm



www.tse.org.tr / Necatibey Cad. No: 112 Bakanlıklar - ANKARA / +90 312 416 62 00

Bu belge hiçbir suretle tahrif edilemez, kısmen veya okunmasını zorlaştıracak şekilde çoğaltılamaz, kazıntı ve silinti yapılamaz.
This certificate cannot be altered, partially duplicated or ereased for misunderstanding.



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	:	Pharmplast S.A.E'. Amria Factory, Amria FreeZone, Alexandria, Egypt
Scope	:	WOUND DRESSING WITH CHLORHEXIDINE GLUCONATE (STERILE)
GMDN Code	:	58301
Classification Rule	:	Rule 4 and 13, Class III
Inspection Report Number	:	2298-MDD-203/2020-02, 2298-MDD-203/2020-05
First Issue Date	:	08.04.2021
Validity Date	:	26.05.2024
Full Quality Assurance Certificate Number	:	1783-MDD-207

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 ... 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-208

Fırat HACIOĞLU

Deputy Director of Directives

ANKARA Rev 00, 08/04/2021

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



www.tse.org.tr / Necatibey Cad. No: 112 Bakanlıklar - ANKARA / +90 312 416 62 00

Bu belge hiçbir suretle tahrif edilemez, kısmen veya okunmasını zorlaştıracak şekilde çoğaltılamaz, kazıntı ve silinti yapılamaz.
This certificate cannot be altered, partially duplicated or creased for misunderstanding.



TÜRK STANDARDLARI ENSTİTÜSÜ
TURKISH STANDARDS INSTITUTION

EC Design Examination Certificate Annex

Certificate No: 1783-MDD-208, Rev 00

Product Type

CERTIFICATE HISTORY		
Date	Revision Number	Reason of Revision
08.04.2021	Rev 00	-

DIFA IV CHG Wound dressing with chlorhexidine gluconate	
Reference No	Size
DİFA IV CHG 76	7 cm x 6 cm
Difa IV CHG 77	7 cm x 7 cm
Difa IV CHG 87	8 cm x 7 cm
Difa IV CHG 810	8 cm x 10 cm
Difa IV CHG 2810	8.25 cm x 10 cm
Difa IV CHG 856	8.5 cm x 6 cm
Difa IV CHG 857	8.5 cm x 7 cm
Difa IV CHG 8510	8.5 cm x 10 cm
Difa IV CHG 97	9 cm x 7 cm
Difa IV CHG 910	9 cm x 10 cm
Difa IV CHG 1012	10 cm x 12 cm
Difa IV CHG 1014	10 m x 14 cm
Difa IV CHG 68	6 cm x 8 cm
Difa IV CHG 79	9 cm x 7 cm
Difa IV CHG 85115	8.5 cm x 11.5 cm
Difa IV CHG 5057	5 cm x 5.7 cm
Difa IV CHG 67	6 cm x 7 cm
Difa IV CHG 657 ADV	6.5 cm x 7 cm
Difa IV CHG 79 ADV	7 cm x 9 cm
Difa IV CHG 85115 ADV	8.5 cm x 11.5 cm
Difa IV CHG 1012 ADV	10 cm x 12 cm
Difa IV CHG 10155 ADV	10 cm x 15.5 cm

Page 1/1



www.tse.org.tr / Necatibey Cad. No: 112 Bakanlıklar - ANKARA / +90 312 416 62 00

Bu belge hiçbir suretle tahrif edilemez, kısmen veya okunmasını zorlaştıracak şekilde çoğaltılamaz, kazıntı ve silinti yapılamaz.
This certificate cannot be altered, partially duplicated or creased for misunderstanding.