



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	:	Pharmplast S.A.E'. Amria Factory, Amria FreeZone, Alexandria, Egypt
Scope	:	GAUZE DRESSING WITH CHLORHEXIDINE DIACETATE (STERILE)
GMDN Code	:	46855
Classification Rule	:	Rule 4 and 13, Class III
Inspection Report Number	:	2294-MDD-201/2020-02, 2294-MDD-201/2020-05
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-221

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>"



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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

Full Quality Assurance Certificate Certification History

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

Certificate No: 1783-MDD-221 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-221, Rev 00

DIFA Plus Gauze dressing with chlorhexidine diacetate	
Reference No	Size
DIFAPLUS5050	5 x 5 cm
DIFAPLUS50100	5 x 10 cm
DIFAPLUS75100	7.5 x 10 cm
DIFAPLUS75150	7.5 x 15 cm
DIFAPLUS75200	7.5 x 20 cm
DIFAPLUS100100	10 x 10 cm
DIFAPLUS100150	10 x 15 cm
DIFAPLUS100200	10 x 20 cm
DIFAPLUS100400	10 x 40 cm
DIFAPLUS200150	20 x 15 cm
DIFAPLUS150150	15 x 15 cm
DIFAPLUS150400	15 x 40 cm
DIFAPLUS200200	20 x 20 cm
DIFAPLUS200400	20 x 40 cm
DIFAPLUS501000	5 x 100 cm
DIFAPLUS751000	7.5 x 100 cm
DIFAPLUS1001000	10 x 100 cm
DIFAPLUS1501000	15 x 100 cm
DIFAPLUS1002000	10 x 200 cm
DIFAPLUS1502000	15 x 200 cm
DIFAPLUS2001000	20 x 100 cm





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DİFAPLUS2002000	20 x 200 cm
DİFAPLUS757000	7.5 x 700 cm
DİFAPLUS1007000	10 x 700 cm
DİFAPLUS1507000	15 x 700 cm

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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	: GAUZE DRESSING WITH CHLORHEXIDINE DIACETATE (STERILE)
GMDN Code	: 46855
Classification Rule	: Rule 4 and 13, Class III
Inspection Report Number	: 2298-MDD-203/2020-02, 2298-MDD-203/2020-05
First Issue Date	: 20.05.2021
Validity Date	: 26.05.2024
Full Quality Assurance Certificate Number	: 1783-MDD-221

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-222

Firat HACIOĞLU

Deputy Director of Directives

ANKARA Rev 00, 20/05/2021

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TÜRK STANDARDLARI ENSTİTÜSÜ
TURKISH STANDARDS INSTITUTION

EC Design Examination Certificate Annex

Certificate No: 1783-MDD-222, Rev 00

Product Type

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

DİFA Plus Gauze dressing with chlorhexidine diacetate	
Reference No	Size
DİFAPLUS5050	5 x 5 cm
DİFAPLUS50100	5 x 10 cm
DİFAPLUS75100	7.5 x 10 cm
DİFAPLUS75150	7.5 x 15 cm
DİFAPLUS75200	7.5 x 20 cm
DİFAPLUS100100	10 x 10 cm
DİFAPLUS100150	10 x 15 cm
DİFAPLUS100200	10 x 20 cm
DİFAPLUS100400	10 x 40 cm
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DİFAPLUS150400	15 x 40 cm
DİFAPLUS200200	20 x 20 cm
DİFAPLUS200400	20 x 40 cm
DİFAPLUS501000	5 x 100 cm
DİFAPLUS751000	7.5 x 100 cm
DİFAPLUS1001000	10 x 100 cm
DİFAPLUS1501000	15 x 100 cm
DİFAPLUS1002000	10 x 200 cm
DİFAPLUS1502000	15 x 200 cm
DİFAPLUS2001000	20 x 100 cm
DİFAPLUS2002000	20 x 200 cm
DİFAPLUS757000	7.5 x 700 cm
DİFAPLUS1007000	10 x 700 cm
DİFAPLUS1507000	15 x 700 cm

