



TÜRK STANDARTLARI 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 Turkey (NB 1783)
Company Name	: ZADİ TIBBİ GEREÇLER SAN. VE TİC. 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 Free Zone, Alexandria, Egypt
Scope	: STERILE SILVER WOUND DRESSING
GMDN Code	: 48124
Classification Rule	: Rule 4 & 13, Class III
Inspection Report Number	: 2296-MDD-202/2020-02, 2296-MDD-202/2020-05
First Issue Date	: 04.02.2021
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-201

Sezai DOĞAN

Director of Directives

ANKARA Rev 00, 04/02/2021



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
TURKISH STANDARDS INSTITUTION

Full Quality Assurance Certificate Certification History

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

Certificate No: 1783-MDD-201, Rev 00

CERTIFICATE HISTORY		
Date	Revision Number	Reason of Revision
04.02.2021	Rev 00	-





TÜRK STANDARTLARI ENSTİTÜSÜ
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Full Quality Assurance Certificate Scope Attachment

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

Certificate No: 1783-MDD-201, Rev 00

Reference No	Size
Difa Ag Non-Adhesive	
Difa Ag 6565	65 x 65 mm
Difa Ag 6080 Tracheostomy	60 x 80 mm
Difa Ag 8080 Tracheostomy	80 x 80 mm
Difa Ag 7575	75 x 75 mm
Difa Ag 100100	100 x 100 mm
Difa Ag 100150	100 x 150 mm
Difa Ag 100200	100 x 200 mm
Difa Ag 150150	150 x 150 mm
Difa Ag 150200	150 x 200 mm
Difa Ag 200200	200 x 200 mm
Difa Ag 200300	200 x 300 mm
Difa Ag 20300 cavity	20 x 300 mm
Difa Ag Sealed Edges	
Difa Ag S 7575	75 x 75 mm
Difa Ag S 100100	100 x 100 mm
Difa Ag S 100150	100 x 150 mm
Difa Ag S 100200	100 x 200 mm
Difa Ag S 150150	150 x 150 mm
Difa Ag S 150200	150 x 200 mm
Difa Ag S 200200	200 x 200 mm
Difa Ag S 200300	200 x 300 mm
Difa Ag S Circular 50	Circular 5 cm
Difa Ag S 120130 Heel	120 x 130 mm





TÜRK STANDARDLARI ENSTİTÜSÜ
TURKISH STANDARDS INSTITUTION

Difa Ag C Sealed Edges	
Difa Ag CS 7575	75 x 75 mm
Difa Ag CS 100100	100 x 100 mm
Difa Ag CS 100150	100 x 150 mm
Difa Ag CS 100200	100 x 200 mm
Difa Ag CS 150150	150 x 150 mm
Difa Ag Adhesive	
Difa Ag Adh 7575	75 x 75 mm
Difa Ag Adh 100100	100 x 100 mm
Difa Ag Adh 100150	100 x 150 mm
Difa Ag Adh 100200	100 x 200 mm
Difa Ag Adh 150150	150 x 150 mm
Difa Ag Adh 150200	150 x 200 mm
Difa Ag Adh 200200	200 x 200 mm
Difa Ag Adh 180165 Concave	180 x 165 mm
Difa Ag Adh 220220 Sacral	220 x 220 mm
Difa Ag C Adhesive	
Difa Ag C Adh 7575	75 x 75 mm
Difa Ag C Adh 100100	100 x 100 mm
Difa Ag C Adh 100150	100 x 150 mm
Difa Ag C Adh 100200	100 x 200 mm
Difa Ag C Adh 150150	150 x 150 mm
Difa Ag C Adh 150200	150 x 200 mm
Difa Ag C Adh 200200	200 x 200 mm
Difa Ag C Adh 200300	200 x 300 mm
Difa Ag Adhesive Plus	
Difa Ag Adh Plus 7575	75 x 75 mm
Difa Ag Adh Plus 100100	100 x 100 mm
Difa Ag Adh Plus 100150	100 x 150 mm
Difa Ag Adh Plus 100200	100 x 200 mm
Difa Ag Adh Plus 150150	150 x 150 mm
Difa Ag Adh Plus 200200	200 x 200 mm
Difa Ag Adh Plus 200300	200 x 300 mm
Difa Ag Basic	
Difa Ag Basic 6565	65 x 65 mm
Difa Ag Basic 6080	60 x 80 mm
Difa Ag Basic 8080	80 x 80 mm
Difa Ag Basic 7575	75 x 75 mm
Difa Ag Basic 100100	100 x 100 mm





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Difa Ag Basic 100150	100 x 150 mm
Difa Ag Basic 100200	100 x 200 mm
Difa Ag Basic 150150	150 x 150 mm
Difa Ag Basic 150200	150 x 200 mm
Difa Ag Basic 200200	200 x 200 mm
Difa Ag Basic Adhesive	
Difa Ag Basic Adh 7575	75 x 75 mm
Difa Ag Basic Adh 100100	100 x 100 mm
Difa Ag Basic Adh 100150	100 x 150 mm
Difa Ag Basic Adh 100200	100 x 200 mm
Difa Ag Basic Adh 150150	150 x 150 mm
Difa Ag Basic Adh 150200	150 x 200 mm
Difa Ag Basic Adh 200300	200 x 300 mm
Difa Ag Basic S	
Difa Ag Basic S 6565	65 X 65 mm
Difa Ag Basic S 6080	60 X 80 mm
Difa Ag Basic S8080	80 X 80 mm
Difa Ag Basic S 7575	75 x 75 mm
Difa Ag Basic S 100100	100 x 100 mm
Difa Ag Basic S 100150	100 x 150 mm
Difa Ag Basic S 100200	100 x 200 mm
Difa Ag Basic S 150150	150 x 150 mm
Difa Ag Basic S 150200	150 x 200 mm
Difa Ag Basic S 200200	200 x 200 mm
Difa Ag Basic S Adhesive	
Difa Ag Basic S Adh 7575	75 x 75 mm
Difa Ag Basic S Adh 100100	100 x 100 mm
Difa Ag Basic S Adh 100150	100 x 150 mm
Difa Ag Basic S Adh 100200	100 x 200 mm
Difa Ag Basic S Adh 150150	150 x 150 mm
Difa Ag Basic S Adh 150200	150 x 200 mm
Difa Ag Basic S Adh 200300	200 x 300 mm
Difa Ag Basic S Adh 200200	200 x 200 mm





TÜRK STANDARTLARI ENSTİTÜSÜ
TURKISH STANDARDS INSTITUTION

EC Design-Examination Certificate

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

Notified Body	: Türk Standartları Enstitüsü (TSE) - Necatibey Cad. No:112 Bakanlıklar Ankara Turkey (NB 1783)
Company Name	: ZADİ TIBBİ GEREÇLER SAN. VE TİC. A.Ş.
Company Address	: Küçükçekmece İkitelli OSB Mah. İmsan B Blok Sok. No:13 Küçükçekmece / İstanbul Turkey
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Full Quality Assurance Certificate Number	: 1783-MDD-201

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 4 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-202

Sezai DOĞAN

Director of Directives

ANKARA Rev 00, 04/02/2021



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TÜRK STANDARDLARI ENSTİTÜSÜ
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EC Design Examination Certificate Annex

Certificate No: 1783-MDD-202, Rev 00

Product Type

CERTIFICATE HISTORY		
Date	Revision Number	Reason of Revision
04.02.2021	Rev 00	-

Reference No	Size
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Difa Ag 150200	150 x 200 mm
Difa Ag 200200	200 x 200 mm
Difa Ag 200300	200 x 300 mm
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Difa Ag C Adh 100200	100 x 200 mm
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Difa Ag Adh Plus 200200	200 x 200 mm
Difa Ag Adh Plus 200300	200 x 300 mm
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