



1783

EU DECLARATION OF CONFORMITY

MANUFACTURER: ZİRVE SAĞLIK HİZMETLERİ

ATAKENT MAH. EGE SK NO:12/65 ÜMRANIYE - ÜMRANIYE / İSTANBUL / TURKEY

under the sole responsibility declares that the following medical device described hereafter:

1) Full Reinforced Apron

Model	GMDN	Apron
510011103	35778	55 g Full Reinforced Apron (Small)
510021103	35778	55 g Full Reinforced Apron (Medium)
510031103	35778	55 g Full Reinforced Apron (Large)
510041103	35778	55 g Full Reinforced Apron (XLarge)
510051103	35778	55 g Full Reinforced Apron (XXLarge)

2) Semi Reinforced Apron

Model	GMDN	Apron
502011103	35778	Semi Reinforced Apron (Small)
502021103	35778	Semi Reinforced Apron (Medium)
502031103	35778	Semi Reinforced Apron (Large)
502041103	35778	Semi Reinforced Apron (XLarge)
502051103	35778	Semi Reinforced Apron (XXLarge)

3) Standard Apron

Model	GMDN	Apron
501011103	35778	35 g Standard Apron (Small)
501021103	35778	35 g Standard Apron (Medium)
501031103	35778	35 g Standard Apron (Large)
501041103	35778	35 g Standard Apron (XLarge)
501051103	35778	35 g Standard Apron (XXLarge)

is in conformity with the European Directive (MDD) 93/42, Annex V.

The device, in accordance with Annex IX of European Directive (MDD) 93/42, has been classified as a class Is (sterile) medical device, according to rule 1.

In order to demonstrate the safety and effectiveness of the medical device, the following European standards were used to assess compliance:

EN ISO 13485, EN ISO 556-1, EN ISO 15223-1, EN 1041+A1, EN ISO 10993-1:2009/AC, EN ISO 10993-5, EN ISO 10993-10, EN ISO11135-1, EN ISO11607-1:2009/A1, EN ISO EN ISO 11607-2:2006/A1, EN ISO14971, EN ISO 11737-1, EN ISO 11737-2, EN ISO14644-1, EN ISO 14644-2, EN ISO 14644-3, EN ISO 14644-4, EN ISO 14644-5, ISO 14698-1, ISO 14698-2, EN ISO 13795-1, ASTM F-1980 07, EN ISO 14937

The compliance of the product to the above mentioned directive and documents is confirmed by the notified body:

TURKISH STANDARDS INSTITUTION (TSE)

Necatibey Cad. No. 112, 06100 Bakanlıklar ,Ankara, Turkey

Notified Body number : 1783

Certificate No.: 1783 -MDD-142

Revision: 1

Approver:

Stamp & signature:

Valid from: 17.01.2021

Place: İSTANBUL / TURKEY

ZİRVE SAĞLIK HİZMETLERİ

Hümeysra ÖZGÖMEC

Atakent Mah. Ege Sok. No:12/65 Ümraniye/İST.

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