



MEDCARE SAĞLIK ÜRÜNLERİ SANAYİ VE TİCARET A.Ş.

FATİH MAH. ÇAMLIK CAD. NO:54 GAZİEMİR İZMİR TÜRKİYE

Subject: Continuation of Surveillance Audits in the Context of MDD Certificate Extension

Tarih: 20.12.2023

Referans No: MY-23-002629

Kiwa Belgelendirme Hizmetleri A.Ş.

İ.T.O.S.B 9. Cadde No: 15

Tepeören Mevkii PK 34959

Tuzla İstanbul

Türkiye

Tel. +90 216 593 25 75

Faks +90 216 593 25 74

posta@kiwa.com.tr

www.kiwa.com

www.1kiwa.com

To Whom It May Concern,

MEDCARE SAĞLIK ÜRÜNLERİ SANAYİ VE TİCARET A.Ş. "Regulation No. 2023/607 of the European Parliament and of the Council amending Regulations (EU) 2017/745 and 2017/746 with the transitional provisions for certain medical devices and medical devices for in vitro diagnostic purposes" Regarding the implementation of its provisions, it has applied to our organization on 18.12.2023 for MDD surveillance audits of the products specified in Annex-I. The contract with Reference Number QUO-182794-MOM7J2 was signed on 19.12.2023 In this context, the company's surveillance audits will be carried out until 26.09.2024 by Kiwa Belgelendirme Hizmetleri A.Ş.

Annex-I: Certificate Information

Notified Body	Products	Certificate Number	Valid Date	Regulation
Kiwa Belgelendirme Hizmetleri A.Ş.	<ul style="list-style-type: none">- Sterile Disposable Drape Packs- Sterile Disposable Drapes- Sterile Disposable Equipment Covers- Sterile Disposable Gowns	1984-MDD-20-649	27.05.2024	93/42/AT

Kind Regards,

Mustafa Serkan Sevimli

Medical Devices Department Manager

KIWA
BELGELENDİRME HİZMETLERİ A.Ş.
Etiler Akademi Sokakı Etiler/Beşiktaş/İstanbul Tuzla Org. San. Bölge
9. Cad. No: 15 Tepeören/ Tuzla/ İSTANBUL/ TÜRKİYE
Tuzla V.D. 620 053 000-1 Tel. No: 365 270
Mersis No: 3623000775700019