



REPUBLIC OF TÜRKİYE
MINISTRY OF HEALTH
MEDICINES AND MEDICAL
DEVICES AGENCY OF TÜRKİYE

CERTIFICATE OF GMP COMPLIANCE
MANUFACTURER OF HUMAN MEDICINAL PRODUCTS

Company name: DEM İLAÇ SAN. VE TİC. A.Ş.

Site address: İnönü Mahallesi Kayışdağı Caddesi No:172/1 Ataşehir / İSTANBUL

Manufacturing authorization date: 05/11/2021

Manufacturing authorization number: TR/SAN/2019/20-2

The manufacturing site above is authorized to perform manufacturing activities for dosage forms listed in Table and is subject to official periodic inspections by our Agency according to the Turkish regulations in force. These regulations and GMP guideline in force are in line with the requirements of PICs and the Directives of European Commission.

On the basis of the regular inspection carried out on 16/10/2024 we certify that the manufacturing site complies with GMP requirements.

TR/GMP/2025/147

10/06/2025


Eray KAPLAN

Vice President of the Agency



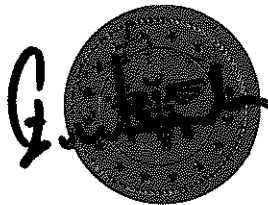
This Certificate until valid 16/10/2027

Table:

Dosage Form	Special requirement (if applicable)	Activities
Human medicinal products	-	Secondary Packaging (Data - matrix processes and Leaflet label etc. processes)
Aseptically prepared products	Non-betalactam Antibiotic, oncologic, cytotoxic, Inhalation, Beta Lactam Antibiotics	Batch release operations of - imported medical products
Non Sterile Products	Oncologic, cytotoxic	Batch release operations of - imported medical products
Biological Medicinal Products	-	Batch release operations of - imported medical products
Blood products	-	Batch release operations of - imported medical products
Biotech Product	-	Batch release operations of - imported medical products
Human/ Animal Extract Based	-	Batch release operations of - imported medical products
Other import processes	-	Physical import facility

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Eray KAPLAN
Vice President of the Agency

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