



DECLARATION OF CONFORMITY

ALDAR MEDİKAL İTHALAT İHRACAT SANAYİ VE TİCARET A.Ş.

ADDRESS : Hasanağa Osb Mah. 15. Cad. No:10 Nilüfer / BURSA

WAREHOUSE ADDRESS : Hasanağa Osb Mah. 15. Cad. No:10 Nilüfer / BURSA

Phone : +90 224 9091390

E-mail : info@aldarmed.com

Declaration of Conformity according to 93/42/EEC Medical Device Directive, Annex V (Manufacture Quality Assurance)

We declare that the products mentioned below meet the medical devices directive requirements of 93/42 / EEC, including the 2007/47 / EC add-on. All relevant supporting documents are available at the manufacturer's facility.

The medical device class is determined as Class IIa according to the Medical Device Directive Annex IX.

Product	Sterile Hypodermic Syringe
Class	93/42 / EEC Medical Device Directive - ANNEX IX, Rule 6, CLASS IIa
Conformity Assessment Procedure	Medical Device Directive 93/42 / EEC, Annex V Production Quality Assurance
GMDN CODE	35904 - Syringe, hypodermic, metered-delivery
Brand	ALDARMED

ALDAR MEDİKAL İTHALAT İHRACAT SANAYİ VE TİCARET A.Ş. declares that the devices under this responsibility comply with the relevant terms and conditions of the Medical Device Directive No. 93/42 / EEC dated June 14, 1993 and subsequent revisions and changes.

ALDAR MEDİKAL İTHALAT İHRACAT SANAYİ VE TİCARET A.Ş. has developed and maintains a documented post marketing surveillance process, including reporting incidents that can be reported to the Authorized Authorities within the scope of the European Medical Devices Compliance System Guidelines.

ALDAR MEDİKAL İTHALAT İHRACAT SANAYİ VE TİCARET A.Ş., declares to maintain the approved quality system to be adequate, effective and sustainable.

The products have been evaluated by the Notified Body for compliance and EC certified.

Product standards are declared in Annex I Applicable Standard List of this declaration.



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Notified Body : Kiwa Belgelendirme Hizmetleri A.Ş.
Notified Body Address : İTOSB 9. Cad. No:15 Tepeören-Tuzla-İstanbul-TÜRKİYE
Identification Number : 1984
Certificate Number : 1984-MDD-20-680
Certificate Issued Date : 02.07.2020
Certificate Validity Date : 27.05.2024

General Manager

Place, Date of Declaration

ALDAR MEDİKAL
İTHALAT İHRACAT SAN. ve TİC. A.Ş.
Hasanağa Osb Mah. 15. Cd. No: 10
Nilüfer/ BURSA Çekirge V.D. 050 094 5955
Mersis No: 0050094595500001

10.08.2021

Annex 1 TD.01-5 List of Applicable Standards

Annex 2 FR.07.01.04 Product List