

MABEL Makina Medikal Sanayi ve Ticaret A.S.
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EU Declaration of Conformity

(No. DC-OZY01-I)

Manufacturer Name : MABEL MAKINA MEDIKAL SANAYI VE TICARET A.S.

Manufacturer Address : Ostim OSB Mah. 1220 Cadde No:35
Yenimahalle-Ankara TURKEY

Registered Trademark : REXXAM

SRN (Single Registration Number) : Manufacturer : TR-MF-000018131
Authorized
Representative : NL-AR-000002643

Authorized Representative : Rexam Co., Ltd. Netherland Office

Address (if applicable) : Steenovenweg 5, 5708HN Helmond, The Netherland


Basic UDI-DI : 82016395268PC

Product Identification : Ophthalmic Examination Unit
Product code : OZY
Other Referance : None
Intended purpose : The OZY Ophthalmic Examination
Unit is designed for devices used
in the diagnosis of eye diseases

Risk Class : Class I medical device without measurement function
Rule 13 Annex VIII of the MDR

This declaration of conformity is issued under the sole responsibility of Mabel Makine Medikal Sanayi ve Ticaret A.S.. We hereby declare that the above-mentioned products meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by IQR International Certification Service Co. Ltd.

Signature:



Date of issue
30.11.2023

Name: Atila KOÇAK
Function Regulatory Manager