MABEL
MABEL MAKİNA MEDİKAL SANAYİ VE TİCARET ANONİM ŞİRKETİ
Ostim Osb Mah 1220 Cad. No: 35
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Tel: + 90 312 256 33 44
Fax:+90312 256 33 45
Ostim Vergi Dairesi Vergi No: 6090721996
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EU Declaration of Conformity

Manufacturer	:	MABEL Makina Medikal Ticaret ve Sanayi A.S. Ostim OSB Mahallesi 1220 Cadde No: 35 Yenimahalle-ANKARA TURKEY
SRN Number	:	TR-MF-000018131
Medical Device	:	Ophthalmic Examination Unit, LIDYA
Ref. Code	:	LIDYA
Basic UDI-DI	:	82016395039NT
Applicable Directives	:	EU Regulation 2017/745 concerning medical devices
Classification (Annex VIII, MDR 2017/745)	:	Class I (Rule 13)
Conformity Assesment Procedure	:	Annex IV

Under our sole responsibility, we state that the "LIDYA" medical device meets all the applicable General Safety and Performance Requirements of Annex I of the Medica Devices Regulation 2017/745 and all the applicable standards.

Applicable harmonized European standards: The list of the applicable standards is reported in the technical file of the device LIDYA.

The manufacturer commits to keep available for the competent authorities the technical documentation quoted in Annex II of European Regulation 2017/745 on medical devices for a period of at least ten years after the last date of product's manufacturing.

Authorized Person Levent KOÇAK
Date 18/10/2021
Signed

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EU Declaration of Conformity

Manufacturer	:	MABEL Makina Medikal Ticaret ve Sanayi A.S. Ostim OSB Mahallesi 1220 Cadde No: 35 Yenimahalle-ANKARA TURKEY
SRN Number	:	TR-MF-000018131
Medical Device	:	Ophthalmic Examination Unit, LIDYA II STATION
Ref. Code	:	LIDYA II STATION
Basic UDI-DI	:	82016395190NY
Applicable Directives	:	EU Regulation 2017/745 concerning medical devices
Classification (Annex VIII, MDR 2017/745)	:	Class I (Rule 13)
Conformity Assesment Procedure	:	Annex IV

Under our sole responsibility, we state that the "LIDYA-II" medical device meets all the applicable General Safety and Performance Requirements of Annex I of the Medica Devices Regulation 2017/745 and all the applicable standards.

Applicable harmonized European standards: The list of the applicable standards is reported in the technical file of the device LIDYA-II.

The manufacturer commits to keep available for the competent authorities the technical documentation quoted in Annex II of European Regulation 2017/745 on medical devices for a period of at least ten years after the last date of product's manufacturing.

Authorized Person Levent KOÇAK
Date 18/10/2021
Signed

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Date:11.02.2022

SUBJECT: FSC CONFIRMATION LETTER

Attention to: **The Ministry of Health of Vietnam**
(Department of Medical Equipment and Construction)

We – **as Mabel Makina Medikal Sanayi Ve Ticaret Anonim Sirketi – Add: Ostim OSB Mahallesi 1220.cad. No:35 Yenimahalle-Ankara/ Turkey** confirmed that our products as we declarated in LOA document sell in Turkey/EU countries/ME and African countries with our FSC as you may see the list of our distrubitor in below.

*Turkey
*France
*Holland
*Portugal
*Spain
*İtaly
*Bosnia
*Romania
*Bulgaria
*Greece
*South Africa
*Saudi
*Libya
*Jordan
*Dubai
*Omman
*Azerbaijan
*Cyprus
*Pakistan
*Algeria
*Egypt
*Palestine

Legal representative of the manufacturer
Levent KOÇAK
General Manager

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