EC DECLARATION OF CONFORMITY

For CE-Marking according to Annex II of Council Directive 93/42/EEC (Rev.2007/47 EC)

Product Name : Hot Air Sterilizers

Product Model : M 3025P – M 420P – M5040P – M 6040P

Product Risk Classification: IIb (Rule 15 of Annex IX of 93/42/EEC-(Rev.2007/47 EC)) : Class 1, type B Equipment (TS EN 60601-1-Electrical Medical Equipment: Requirements for Basic Safety and Required Performance)

WE:

ELEKTRO-MAG Laboratuvar Aletleri San ve Tic. A.S

O.S.B. Demirciler Sitesi B7 Blok No:153 IKITELLI

ISTANBUL- TURKEY (production&design)

ELEKTRO-MAG Laboratuvar Aletleri San ve Tic. A.S

Turgut Ozal Cad. Karagul Is Merkezi No:84/5 Fındıkzade/Fatih

ISTANBUL-TURKEY (sales)

DECLARE THAT THE PRODUCTS LISTED ON THE ANNEX MEET THE APPLICABLE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC-(Rev.2007/47 EC) of June 14th 1993 and RELATED HARMONISED PROCEDURES LISTED ON THE ANNEX.

CE Certificate Number : 1984-MDD-18-509
Certificate Expiration Date : 27.05.2024
GMDN Code : 35364

IN THE CERTIFICATION OF LISTED PRODUCTS AGAINST THE DIRECTIVE 93/42/EEC-(Rev.2007/47 EC) ***KIWA Belgelendirme Hizmetleri A.S.*** HAS BEEN INVOLVED AS NOTIFIED BODY WITH THE REGISTRATION NUMBER 1984.

KIWA Belgelendirme Hizmetleri A.S.

ITOSB 9. Cad. No:15 Tepeören Tuzla Istanbul, 34959, Turkey

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Date: 2022.1
Reason: Mol
Location: Mo

Coşkun YILDIZ
Production Manager
Basaksehir/Istanbul
01.08.2022

M. Demirhan CARDA
Plant Manager
Basaksehir/Istanbul
01.08.2022

ANNEX TO EC-DECLARATION OF CONFORMITY

PRODUCT MODELS AND TYPES

MODEL	M 3025P	M 420P	M 5040P	M 6040P
Installed Power	850 W	1200 W	1750 W	1750 W
Net volume (litres)	24	48	100	120

APPLIED STANDARDS

EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 14971:2010	Medical devices - Application of risk management to medical device
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
TS EN 6073:1988	Electrically operated dry air sterilizer standard
EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
EN 62304:2006	Medical device software - Software life-cycle processes
EN ISO 20417: 2021	Medical devices - Information to be supplied by the manufacturer

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