

Manufacturer: KEN HYGIENE SYSTEMS A/S
Adresse: 5672 Broby, Bøgebjerg vej 60, Denmark
Tel: +45 62 63 10 91
Fax: +45 62 63 16 07

Hereby declares that:

According to Annex II to Council Directive 93/42/EEC of June 14, 1993

KEN Washer-disinfector, type: MAT LD 500 Machine No.:

GMDN Term: Surgical utensil washer/decontaminator. GMDN Code: 35424

Is produced in accordance with - and meets the requirements of:

Council Directive 93/42 EEC with supplement 2007/47/EC (Directive for Medical Device Class IIb products)

and complies with the following international standards and legislation:

Title:	Subject:
MDR 2017/745	Medical devices Regulation (Transitional provisions)
EN ISO 13485:2016 +A11:2021	Medical devices - Quality management system
EN ISO 14971:2019 +A11:2021	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2021	Medical devices - Symbols to be used
EN ISO 15883-1:2009 +A11:2014	Washer disinfectors Part 1
EN ISO 15883-2:2009	Washer disinfectors Part 2
EN ISO 15883-5:2021	Washer disinfectors Part 5
EN 60601-1-2:2015	Electromagnetic disturbances - Requirements and tests (EMC)
EN 62304:2006 + A1:2015	Medical device software - Software life-cycle processes
EN 62366-1:2015 +A1:2020	Application of usability engineering to medical devices
EN 61010-1:2010 +A1:2019	Safety requirements Part 1
EN 61010-2-040:2021	Safety requirements Part 2

We declare compliance of the above medical device with the requirements of the Council Directive 93/42/EEC of June 14, 1993, the Norwegian Implementation of the same directive, and their amendments. Any modification of the medical device not authorized by us will invalidate this declaration.

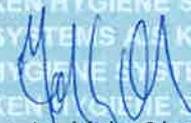
The Route to Compliance: 93/42/EEC Medical devices directive, Annex II excluding section 4

EU Certificate: 10000379653-PA-NA-DNK Rev 0.0

Certified by: DNV Product Assurance AS

Number: 2460

Brobyværk date:2022-04-29


John Veje Olesen
Managing Director


2460