eurofins

QUALITY MANAGEMENT SYSTEM

EU-CERTIFICATE

Regulation (EU) 2017/745

Manufacturer:	KiiltoClean Oy Tengströminkatu 6 20360 Turku Finland
Single registration number:	FI-MF-000001622
Conformity assessment procedure:	Regulation (EU) 2017/745 Annex IX
Device category:	MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing
Date of expiry:	11 May 2027

The manufacturer's quality management system covering the device category has been assessed and approved in accordance with the Annex IX to Regulation (EU) 2017/745. Approval shall be valid until the expiry date provided that the manufacturer fulfills the obligations imposed by Annex IX in Regulation. The products covered by the certificate and the details related to the maintenance of this certificate are specified in the attachment to the certificate.

Date of issue: 12 May 2022

Aliisa Siljander

Laura Petäjämäki

Certificate no:

CR-03-1201-785-22

Notified Body no. 0537:
Eurofins Electric & Electronics Finland Oy
Kivimiehentie 4
FI-02151 Espoo, FINLAND

Information about the examinations and tests as per MDR Annex XII, section 10, is available upon request from EES-medical@eurofins.fi.

Attachment 1 to the certificate no: CR-03-1201-785-22

Manufacturer:	KiiltoClean Oy Tengströminkatu 6 20360 Turku Finland
Other sites covered by the quality management system:	KiiltoClean Oy Tuotekatu 14 21200 Raisio Finland
Single registration number:	FI-MF-000001622
Conformity assessment procedure:	Regulation (EU) 2017/745 Annex IX
Limitations to the validity of the certificate:	No limitations

The certificate covers the following products:

MD-codes:	MDN 1211 MDT 2006, MDT 2011	
Device category:	MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	
Product name	*Product details*	
Kiilto Pro Erisan Oxy+	Model	50 g
	Nomenclature code	D050101 Peracetic and acetic acid with hydrogen peroxide for the disinfection of medical devices
	Risk class	IIa
Kiilto Pro Easydes	Model	500 ml 5 l Wipes 16 pcs Wipes 30 pcs
	Nomenclature code	D0701 Ethanol for the disinfection of medical devices
	Risk class	IIa
Kiilto Pro MD Des Etanol 75	Model	1000 ml
	Nomenclature code	D0701 Ethanol for the disinfection of medical devices
	Risk class	IIa

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Product name	*Product details*	
Antibac Overflatedesinfeksjon 75%	Model	250 ml 750 ml 1000 ml
	Nomenclature code	D0701 Ethanol for the disinfection of medical devices
	Risk class	IIa
Antibac Dental 75% overflatedes	Model	1000 ml
	Nomenclature code	D0701 Ethanol for the disinfection of medical devices
	Risk class	IIa
Kiilto Pro MD Des Etanol 75+	Model	1000 ml
	Nomenclature code	D0701 Ethanol for the disinfection of medical devices
	Risk class	IIa
Antibac Overflatedesinfeksjon 75% m. tensid	Model	750 ml
	Nomenclature code	D0701 Ethanol for the disinfection of medical devices
	Risk class	IIa
Antibac Dental Overflate+ 75% m/tensid	Model	750 ml
	Nomenclature code	D0701 Ethanol for the disinfection of medical devices
	Risk class	IIa
Antibac Overflatedesinfeksjon Premium 88,8%	Model	750 ml
	Nomenclature code	D0701 Ethanol for the disinfection of medical devices
	Risk class	IIa
Kiilto Pro MD Des IPA 45+	Model	1000 ml 5000 ml
	Nomenclature code	D0702 Isopropyl alcohol for the disinfection of medical devices
	Risk class	IIa
Kiilto Pro MD Instru Des 45+	Model	1000 ml 3000 ml
	Nomenclature code	D0702 Isopropyl alcohol for the disinfection of medical devices
	Risk class	IIa

Attachment 1 to the certificate no: CR-03-1201-785-22

Product name	*Product details*	
Kiilto Pro Erisan Des	Model	500 ml 3 l
	Nomenclature code	D0902 Associated ammonium salts for the disinfection of medical devices
	Risk class	IIa

The validity and maintenance of this certificate require the surveillance performed by the notified body in accordance with the MDR Annex IX (3). The surveillance includes annual quality management system audits at the manufacturer's premises as well as regular unannounced audits. If necessary, all audits may be carried out at the premises of the manufacturer's suppliers and/or subcontractors. The surveillance also includes the assessment of the significant changes planned by the manufacturer and the assessment of the technical documentation in accordance with the notified body's sampling plan (IIa and IIb).

Date of issue of this attachment: 12 May 2022

Aliisa Siljander Laura Petäjämäki

Change history of the certificate:				
Certificate no	**Revision**	**Status of the certificate**	**Date of issue**	**Description of the change**
CR-03-1201-785-22	01	Initial certification	12.05.2022	Initial revision