EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Ecolab Deutschland GmbH

Ecolab-Allee 1
40789 Monheim am Rhein
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Medical Device Disinfectants according to annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	002201 MR2
Certificate unique ID	170763851
Effective date	2020-02-05
Expiry date	2024-05-26
Frankfurt am Main	2020-02-05

DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

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Device family	Device	Class
Disinfectant for operating theater textiles	Ozonit BNL	IIa
Universal disinfecting detergent for operating theater textiles	Eltra medical	IIa
Disinfectant for automated instrument re-processors	Sekumatic FD Sekumatic FDR	IIb
Disinfectant for dialysis machines	Sekumatic FDG Maranon H Peresal	IIb
Disinfectant for manual re-processing of medical instruments	Sekucid konz Sekucid N / Sekucid N coloré Sekudrill Seku Extra Sekulyse Sekumed Sekusept aktiv Sekusept easy Sekusept Extra N Sekusept forte Sekusept forte S Sekusept Plus with variants: PracticeProtect Instrument Disinfection & Cleaning Liquid Glucoprotamin Sekusept Pulver / Poeder / Poudre / Sekusept Pulver classic / Sekupoudre Sekusept Basic Test Product PD-37	IIb
Disinfectant for the automated chemo-thermal reprocessing of bed pans	Kodra Des	IIa

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Device family	Device	Class
Surface disinfectant for medical surfaces and inventory	Incides N	IIa
	Incidin active	IIa
	Incidin Extra N	IIa
	Incidin foam	IIa
	Incidin liquid (Spray) with variants:	IIa
	PracticeProtect	IIa
	Surface Disinfection Alcohol (60%) Spray	IIa
	Incidin OxyDes	IIa
	Incidin perfekt	IIa
	Incidin Plus	IIa
	Incidin Pro	IIa
	Incidin Rapid	IIa
	Incidin Alcohol Wipe	IIa
Disinfectants for medical surfaces incl. probes	Incidin OxyFoam with variants:	IIb
	PracticeProtect	IIb
	Surface Disinfection Hydrogen Peroxide (1.5%) Foam Spray	
	Incidin OxyFoam S with variants:	IIb
	OXY FOAM WS	IIb
	Incidin OxyWipe with variants:	IIb
	PracticeProtect	IIb
	Surface Disinfection Hydrogen Peroxide (1%) Wipes	
	Incidin OxyWipe S with variants:	IIb
	OXY WIPE WS	IIb
Disinfectant for automated endoscope re-processors	Disinfectant ETD	IIb
	Olympus EndoDis Pro	IIb
Disinfectant for machine preparation of rigid and flexible endoscopes	Olympus EndoDis	IIb
Disinfectant and cleaning agent for dental suction systems	Dekaseptol Gel	IIa
Prion inactivating cleaner for medical Instruments in automated reprocessors	MetalClean	IIb