



# 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.



**Annex to certificate**  
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<b>Device family</b>	<b>Device</b>	<b>Class</b>
<b>Disinfectant for operating theater textiles</b>	Ozonit BNL	Ila
<b>Universal disinfecting detergent for operating theater textiles</b>	Eltra medical	Ila
<b>Disinfectant for automated instrument re-processors</b>	Sekumatic FD Sekumatic FDR	Ilb
<b>Disinfectant for dialysis machines</b>	Sekumatic FDG Maranon H Peresal	Ilb
<b>Disinfectant for manual re-processing of medical instruments</b>	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	Ilb
<b>Disinfectant for the automated chemo-thermal reprocessing of bed pans</b>	Kodra Des	Ila



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<b>Device family</b>	<b>Device</b>	<b>Class</b>
<b>Surface disinfectant for medical surfaces and inventory</b>	Incidin 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
	<b>Disinfectants for medical surfaces incl. probes</b>	Incidin OxyFoam with variants:
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	
<b>Disinfectant for automated endoscope re-processors</b>	Disinfectant ETD	IIb
	Olympus EndoDis Pro	IIb
<b>Disinfectant for machine preparation of rigid and flexible endoscopes</b>	Olympus EndoDis	IIb
<b>Disinfectant and cleaning agent for dental suction systems</b>	Dekaseptol Gel	IIa
<b>Prion inactivating cleaner for medical Instruments in automated reprocessors</b>	MetalClean	IIb