



# 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 medical

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	170650586
Effective date	2016-06-02
Expiry date	2020-06-04
Frankfurt am Main	2016-06-02

### 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	IIa
<b>Universal disinfecting detergent for operating theater textiles</b>	Eltra medical	IIa
<b>Disinfectant for automated instrument re-processors</b>	Sekumatic FD Sekumatic FDR	IIb
<b>Disinfectant for dialysis machines</b>	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 Sekusept Pulver / Poeder / Poudre / Sekusept Pulver classic / Sekupoudre Sekusept Basic Test Product PD-37	IIb
<b>Disinfectant for the automated chemo-thermal reprocessing of bed pans</b>	Kodra Des	IIa



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<b>Device family</b>	<b>Device</b>	<b>Class</b>
<b>Surface disinfectant for medical surfaces and inventory</b>	Incides N	Ila
	Incidin active	Ila
	Incidin Extra / Virufen / Diesin HG	Ila
	Incidin Extra N	Ila
	Incidin foam	Ila
	Incidin liquid (Spray)	Ila
	Incidin OxyDes	Ila
	Incidin perfekt	Ila
	Incidin Plus	Ila
	Incidin Pro	Ila
	Incidin Rapid	Ila
	Incidin Spezial Spray	Ila
	Incidur	Ila
	Incidur Spray	Ila
	Minudes	Ila
Minutil	Ila	
<b>Disinfectants for medical surfaces incl. probes</b>	Incidin OxyFoam	Ilb
	Incidin OxyFoam S	Ilb
	Incidin OxyWipe	Ilb
	Incidin OxyWipe S	Ilb
<b>Disinfectant for automated endoscope re-processors</b>	Disinfectant ETD	Ilb
<b>Disinfectant for machine preparation of rigid and flexible endoscopes</b>	Olympus EndoDis	Ilb
<b>Disinfectant and cleaning agent for dental suction systems</b>	Dekaseptol Gel	Ila
<b>Prion inactivating cleaner for medical Instruments in automated reprocessors</b>	MetalClean	Ilb