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	170602411
Effective date	2015-06-05
Expiry date	2020-06-04
Frankfurt am Main	2015-06-01

DQS Medizinprodukte GmbH

Frank Graichen
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

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

20120803/2/EN380308

Annex to Certificate
Certificate registration No.: 002201 MR2
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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 Sekusept Pulver / Poeder / Poudre / Sekusept Pulver classic / Sekupoudre STERICLEAN PRED	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 Incidin active Incidin Extra / Virufen / Diesin HG Incidin Extra N Incidin foam Incidin liquid (Spray) Incidin OxyDes Incidin perfekt Incidin Plus Incidin Pro Incidin Rapid Incidin Spezial Spray Incidur Incidur Spray Minudes Minutil	IIa
Disinfectant for automated endoscope re-processors	Disinfectant ETD	IIb
Disinfectant for machine preparation of rigid and flexible endoscopes	Olympus EndoDis	IIb
Disinfectant and cleaning agent for dental suction systems	Dekaseptol Gel	IIa

ECOLAB EMEA

KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY	Revision: 4
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Wir / We

Name + Adresse der Firma: Name + address of manufacturer:	**Ecolab Deutschland GmbH** **Ecolab-Allee 1** **40789 Monheim am Rhein - Germany**

erklären in alleiniger Verantwortung, dass / declare on our own responsibility that

das Medizinprodukt / the medical device	Name / Name **Sekusept® aktiv**
Typ / type	**Desinfektionsmittel für manuelle Aufbereitung von medizinischen Instrumenten** **Disinfectant for manual re-processing of medical instruments**
Klasse / class gemäß / according	**II b** Anhang IX, Regel 15 / annex IX, rule 15

allen Anforderungen der Richtlinie 93/42/EWG entspricht.
meets all the provisions of the Directive 93/42/EEC

Angewandte harmonisierte Normen: Applied harmonized standards:	**ISO 14971** **ISO 13485**	
Benannte Stelle / Notified body	DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Deutschland **CE 0297**	
Konformitätsbewertungsverfahren Conformity assessment procedure	Artikel 11 Absatz 3a 93/42/EEC gem. Anhang II article 11 paragraph 3a 93/42/EEC acc. to annex II	
Gültigkeitsdauer / Validity	04.06.2020	

Monheim am Rhein, 03.06.2015

Dr. Susanne Frixel
Principal Regulatory Specialist I
Regulatory Affairs EMEA

Dr. Stefan Jäger
Senior Program Leader
RD&E Healthcare EMEA

Ort, Datum / place, date	Name und Funktion / name and function

Certificate Of Analysis

Material number	3050530
Product name	SEKUSEPT AKTIV 4X1.5KG
Batch number	4269FM0313
Production date	2019/06/27
Expiry date	2021/06

Parameter	Reference value	Unit	Measurement	Method
Optical Evaluation - Eur. Reg.-Q-A 1000.0	White granulate with blue springes	unitless	ok	915-A
Aroma - Eur. Reg.-Q-A 1008.0	According to standard	unitless	ok	916-A
pH of Solutions EU Pharm. Q-P 1042.1	7,5- 8,5	unitless	7,9	973-A
Bulk Density -EU Reg-Q-P-1465.0	750 - 850	g/l	800	1946-A
Optical Evaluation - Eur. Reg.-Q-A 1000.0	Clear and slightly blue solution	unitless	ok	915-A
Peracetic Acid-EU VTA32X08003.E2	> 2000	ppm	2560	1976-A

Above mentioned data are the results of our quality inspection at time of product release. They do not release the customer from a receiving control and they are no assurance of certain characteristics or of the suitability for a concrete use. Due to various possible influences during use of our product they don't relieve the user from own tests.

EDP – Performed. Content of the certificate of analysis is binding without sign and company stamp