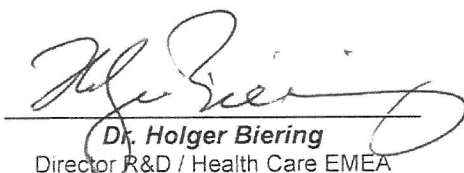


Ecolab GmbH & Co OHG develops and produces certain chemical preparations to be used as cleaning agents for medical devices and auxiliaries in the context of reprocessing of medical devices. According to their intended use these products are auxiliaries to medical devices in the sense of the European Directive 93/42 EEC.

We hereby declare conformity according to article 11, paragraph (5) of the EEC directive following Annex VII for these medical devices which belong to class 1 according to Annex IX, rule 1. The brand names belonging to this product group, are identified in the class 1 Medical Device List. The Safety Officer is authorized to control the lists of Medical Devices.

Specifically we assure by a comprehensive quality management system that the essential requirements of Annex I are fulfilled as well as all further requirements of Annex VII to the directive.

Düsseldorf, May 6<sup>th</sup>, 2008



**Dr. Holger Biering**  
Director R&D / Health Care EMEA



**Dipl. Ing. Dieter Wirbals**  
Manager Regulatory Quality Systems EMEA

Current No.	Product – name	Product - category	Medical Devices Class
1	Entkalker	Cleaner and descaler for dialysis machines	I
2	Sekusept Pulver Aktivator	Booster for Sekusept Powder	I
3	Sekusept Cleaner	Cleaning booster for Sekusept forte and other own disinfectants for medical instruments	I
4	Sekumatic FR	Cleaner for medical instruments in automated re-processors	I
5	Sekumatic FRE	Cleaner for medical instruments in automated re-processors	I
6	Sekumatic PR	Cleaner for medical instruments in automated re-processors	I
7	Sekumatic FK	Rinsing agent for medical instruments in automated re-processors	I
8	Sekumatic FNP	Cleaner for medical instruments in automated re-processors	I
9	Sekumatic FNZ	Cleaner for medical instruments in automated re-processors	I
10	Sekumatic FTP	Lubricant for medical instruments in automated re-processors	I
11	Sekumatic IS	Lubricant for medical instruments	I
12	Cleaner ETD	Cleaner for automated endoscope re-processors	I
13	Sekumatic FKN	Rinsing agent for medical instruments and other medical devices in automated re-processors	I

Safety officer according to § 30 MPG:

*R. Glasmacher*  
(R. Glasmacher)

Quality Manager:

*W. Wirbals*  
(D. Wirbals)

Current No.	Product – name	Product - category	Medical Devices Class
14	CD 20	Cleaner for surfaces and inventory in OR	I
15	Sedigerm	Decontamination agent for medical surfaces	I
16	Savogerm Instruments	Cleaning and decontamination agent for medical instruments	I
17	Sekumatic FKS; additional names Sicmatic N and Servomatic	Rinsing agent and softener for bedpan machines	I
18	Sekumatic FRK	Detergent, softener and rinsing agent for bedpan machines	I
19	Olympus EndoAct	Activator for Olympus EndoDis	I
20	Olympus EndoDet	Cleaner for automated endoscope re-processors	I
21	Activator for Sekusept easy	Accessories for instrument disinfectant Sekusept easy, pH – stabilizer	I
22	Aktivator for Sekusept Pulver classic	Booster for Sekusept powder	I
23	Sekumatic OXIVARIO	Cleaning booster for Sekumatic FR or other alkaline cleaner for automated reprocessing of medical instruments	I
24	Seku zyme	Cleaner for medical instruments	I
25	Sekumatic MulticClean	Cleaner for medical instruments in automated re-processors	I
26	Sekumatic NeutraClean	Cleaner for medical instruments in automated re-processors	I

Safety officer according to § 30 MPG:

*R. Harnisch*  
(R. Glasmacher)

Quality Manager:

*W. Wirth*  
(D. Wirths)

Current No.	Product – name	Product - category	Medical Devices Class
27	Sekusept MultiEnzyme	Cleaner for medical instruments	I
28	Sekusept MultiEnzyme P	Cleaner for medical instruments	I

Safety officer according to § 30 MPG:

R. Glasmacher  
(R. Glasmacher)

Quality Manager:

W. Wirbals  
(D. Wirbals)