Declaration of Conformity (7/7)

according to Annex II of 93/42 EEC

Ecolab Deutschland GmbH develops and produces medical devices, which are distributed by their affiliated companies throughout Europe.
The medical devices are (beside others):

- **Disinfectants for Dental Suction Systems**

These disinfectants belong to class II a (see annex IX, rule 15, of 93/42 EEC) and are named in the class II a Medical Device List. This declaration is valid for the device no. 33 of this list. The Medical Device Safety Officer is authorized to control the lists of Medical Devices.

For this group of disinfectants we hereby declare conformity to EEC directive 93/42. Specifically we assure by our quality management system that the essential requirements of Annex I are fulfilled as well as all requirements of Annex II for products of class II a. The brand names of the disinfectants are given in amendments to this declaration.

For this group of medical devices we have performed the conformity assessment procedure according to Annex II following article 11, paragraph 3 (a) of the directive. We have informed the competent authority that the Notified Body DQS has been ordered to perform the conformity assessment procedure. We submit the list of class II a Medical Devices to the Notified Body during audits and in case of changes. We inform the competent authority about product introduction or deletion according to local regulations.

We are committed to keep the approved quality management system efficacious. We will inform the Notified Body about any plan for substantial changes to the quality management or this group of medical devices, prior to the implementation.

Düsseldorf, August 20th, 2009

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