



EC declaration of conformity

according to Annex II - excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

DECLARATION OF CONFORMITY

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| Medical Device | thermosept® ED |
| Manufacturer | Schülke & Mayr GmbH Robert-Koch-Str. 2 22851 Norderstedt |
| Notified Body | DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Ident.No.: 0297 |
| Classification acc. to Directive 93/42/EEC, Annex IX, Rule 15 | IIb |
| Product group | Disinfectant, endoscopes |
| Product category | 05 - Hospital hardware |
| Issued CE certificates | EN ISO 9001 – Cert. Reg. No. 004567 QM08 EN ISO 13485 – Cert. Reg. No. 004567 MP29 Annex II – Cert. Reg. No. 004567 MR2 |
| Standards applied | Applied standards are listed in Sec. 2.4 of the technical documentation. Location of technical documentation: Schülke & Mayr GmbH, Reg. Affairs |

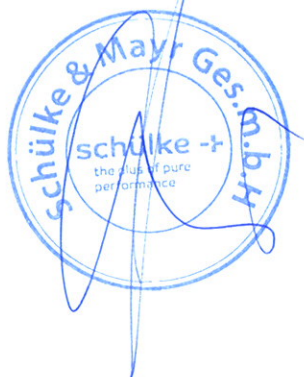
We herewith declare that the described device corresponds to the essential requirements of the EEC directive concerning medical devices.

I, the undersigned declare that Schülke bears the sole responsibility for issuing this Declaration

Norderstedt, 27.11.2014

A handwritten signature in blue ink, appearing to read "Melanie Schmidt", written over a horizontal line.

i.V. Melanie Schmidt
Regulatory Affairs



This Declaration is valid until an updated version has been issued, but not longer than 3 years.