

EC declaration of conformity

Declaration of Conformity

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|---|---|----------------|------------|
| Medical Device name | mikrozid[®] universal wipes | | |
| Formulation No. | F01 | | |
| Product group | Disinfectant, medical device surfaces | | |
| Product Category | 05 - Hospital hardware | | |
| Intended Purpose | surface disinfectant | | |
| Risk Class | II a | | |
| according to Directive 93/42/EEC | annex | IX | |
| Standards applied | EN ISO 13485 additional standards see technical documentation Schülke & Mayr GmbH, Regulatory Affairs | | |
| Manufacturer | Schülke & Mayr GmbH Robert-Koch-Str. 2 22851 Norderstedt Germany | | |
| according to Directive 93/42/EEC | | | |
| Notified Body | DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Germany Ident.No.: 0297 | | |
| Conformity Assessment Procedure | Annex II excluding section 4 | | |
| according to Council Directive 93/42/EEC | | | |
| Issued Certificates | Annex II 93/42/EEC | Cert. Reg. No. | 004567 MR2 |
| Version | 3.0 | | |


Schülke & Mayr GmbH herewith declares that the device covered by this declaration is in conformity with the Council Directive 93/42/EEC concerning medical devices.

Schülke & Mayr GmbH declares that Schülke & Mayr GmbH bears the sole responsibility for issuing this Declaration

Norderstedt

06.05.2019

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Director Quality and HSE
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