schülke -}

EC declaration of conformity

05 - Hospital hardware

surface disinfectant

Medical Device name

mikrozid® sensitive liquid

Disinfectant, medical device surfaces

Formulation No.

Product group

Product Category

Intended Purpose

Risk Class

according to Directive 93/42/EEC

IX

F02

II a

Standards applied

EN ISO 13485

additional standards see technical documentation

Schülke & Mayr GmbH, Regulatory Affairs

Manufacturer

Notified Body

according to Directive 93/42/EEC

Schülke & Mayr GmbH Robert-Koch-Str. 2

22851 Norderstedt

Germany

DQS Medizinprodukte GmbH

August-Schanz-Str. 21 60433 Frankfurt am Main

Germany

Ident.No.: 0297

Conformity Assessment Procedure

according to Council Directive 93/42/EEC

Issued Certificates

Annex II excluding section 4

Annex II 93/42/EEC

Cert. Reg. No.

004567 MR2

Version

1.0

Schülke & Mayr GmbH herewith declares that the device covered by this declation 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

15.11.2021

15.11.2021

ppa. Dr. Uwe Berlekamp

Director Business Line Healthcare

Schülke & Mayr GmbH

ppa. Jörn Ahlsdorff

Director Industrial Operations International Industrial Operations

Schülke & Mayr GmbH