

EC Declaration of Conformity

Manufacturer:

Suzhou Semorr Medical Technology Co., Ltd.

Address:

3rd F, Bldg.1#, North MD Industry Park, No 188

Jialingjiang Rd.,

Hi-tech Dist., Suzhou, China, 215163

Authorized

representative:

Shanghai International Holding Corp. GmbH (Europe)

Address:

Eiffestrasse 80, 20537 Hamburg, Germany

Product Name:

Surgical Microscope

Model Number:

DOM3000A, DOM3000B, DOM3000C, DOM3000D.

DOM3000E

Classification:

Class I (Rule 12 of Annex IX of the Directive 93/42/EEC)

We hereby declare that the above-mentioned products meet the provisions of the following EC Council Directives.

1. The essential requirements set out in European Medical Device Directive 93/42/EEC (MDD), Annex I

2. The applicable requirements of a quality management system according to Annex II of Directive 93/42/EEC.

3. The assessment criteria of European Medical Device Directive 93/42/EEC (MDD), Annex VII

The above-mentioned declaration of conformity is exclusively under the responsibility of

Company:

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General Manager Issue Date: Aug 3rd, 2020