

DoC-SURGERY-201908-001(V4.0)



EC Declaration of Conformity

Manufacturer: Nanjing Mindray Bio-Medical Electronics Co., Ltd.
666# Middle Zhengfang Road, Jiangning, 211111 Nanjing, Jiangsu,
P.R.China

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
(DIMDI No.: DE/0000040627)

Product Name: Insufflator

Model: HS-50F, HS-50V, HS-50H, HS-50S, HS-30S

UMDNS Code: 12144 **GMDN Code:** 16849

Classification: IIa (According to Annex IX, Rule 11 of Directive 93/42/EEC)

Compliance of the designated product(s) with the directives has been assessed following the procedure relating to the EC Declaration of Conformity set out in Annex II, Article 3 of Directive 93/42/EEC and has been certified by the Notified Body.

TÜV SÜD Product Service GmbH

Ridlerstraße 65, 80339 MÜNCHEN, Germany

Certificate No.: G1 070744 0016

Issue date: 2020-03-04

Expiry date: 2024-05-26

We, declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for Medical Device, as amended by 2007/42/EC. All supporting documentations are retained under the premises of the manufacturer. This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Standards Applied:

EN ISO 13485:2016/ISO 13485:2016

EN ISO 14971:2012/ISO 14971:2007

EN 60601-1:2006+A1:2013/IEC 60601-1:2005+A1:2012

IEC 60601-2-18:2009/ EN 60601-2-18:2015

EN 60601-1-2:2015/IEC 60601-1-2:2014

IEC 60601-1-6:2010+AMD1:2013/EN 60601-1-6:2010/A1:2015

IEC 62366-1:2015/EN 62366-1:2015

IEC 62304:2006+A1:2015/EN 62304:2006/A1:2015

EN 1041:2008

ISO 15223-1:2016

EN ISO 10993-1:2009+AC:2010

EN ISO 10993-5:2009

EN ISO 10993-10:2013

ISO 17664:2017

Start of CE-Marking:

2019-8-28

Signature:

Zhai Pei

Place, Date of Issue:

Nanjing, 2020.12.30

Name of Authorized Signatory: Mr. Zhai pei

Position Held in Company:

Manager, Technical Regulation



DoC-SURGERY-201803-001(V4.0)



EC Declaration of Conformity

Manufacturer: Nanjing Mindray Bio-Medical Electronics Co., Ltd.
666# Middle Zhengfang Road, Jiangning, 211111 Nanjing, Jiangsu,
P.R.China

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
(DIMDI No.: DE/0000040627)

Product Name: Rigid Endoscope
Model: M 01000A/M 01030A/M 01000/M 01030
G 01000A/G 01030A/G 01000/G 01030
UMDNS Code: 20475 **GMDN code:** 12291

Classification: IIa (According to Annex IX, Rule 6 of Directive 93/42/EEC)

Compliance of the designated product(s) with the directives has been assessed following the procedure relating to the EC Declaration of Conformity set out in Annex II, Article 3 of Directive 93/42/EEC and has been certified by the Notified Body.

TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 MÜNCHEN, Germany

Certificate No.: G1 070744 0016

Issue date: 2019-08-27

Expiry date: 2024-05-26

We, declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for Medical Device, as amended by 2007/42/EC. All supporting documentations are retained under the premises of the manufacturer. This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

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EN ISO 13485:2016/ISO 13485:2016

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IEC 60601-1-6:2010+AMD1:2013/EN 60601-1-6:2010/A1:2015

IEC 62366-1:2015/EN 62366-1:2015

EN 60601-1:2006+A1:2013/IEC 60601-1:2005+A1:2012

IEC 60601-2-18:2009

EN 1041:2008

EN ISO 10993-1:2009+AC:2010

EN ISO 10993-5:2009 EN ISO 10993-10:2013

ISO 15223-1:2016

ISO 8600-1:2015

ISO 8600-3:1997+A1:2003

ISO 8600-4:2014

ISO 8600-5:2005

ISO 8600-7:2012

ISO 17664:2004

Start of CE-Marking: 2018-3-13

Signature:

Li Xiaoqiao

Place, Date of Issue:

Nanjing, 2019-9-27

Name of Authorized Signatory: Mr. Li Xiaoqiao

Position Held in Company: Management Representative

