



RENOSEM Co.,Ltd.

Unit 103-806, 397, Seokcheon-ro, Bucheon-si, Gyeonggi-do, Korea

EC Declaration of Conformity

We herewith declare that the under-mentioned products are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by Directive 2007/47/EC. All supporting documentation is retained under the premises of the manufacturer.

Product Name: Sterilization Agent

GMDN Code No. : 18-005, Germicides, hydrogen peroxide

Model Name: RENO-SA or FINO-SA30

Classification : Class IIb (MDD 2007/47/EC, Annex IX Rule 15)

Conformity Assessment Route : Annex II, Excluding Section 4, MDD 2007/47/EC

Notified Body : SGS UK Ltd.

Unit 202B, World Parkway Weston-Super-Mare Somerset
BS 22 6WA United Kingdom

Standards applied : ISO13485:2016, EN ISO14971:2012, EN1041:2008,
EN ISO 15223-1:2016, ISO14937:2009

Manufacturers Registered Name : RENOSEM Co., Ltd.

EC Representative : MT-Promedt Consulting GmbH

Altenhofstrasse 80 66386 St. Ingbert, Germany



RENOSEM CO.,LTD

Signature :

PRESIDENT / K. S. LEE

Date: 04 Sep 2018

Kwang-Sik Lee/ CEO



RENOSEM Co.,Ltd.

Unit 103-806, 397, Seokcheon-ro, Bucheon-si, Gyeonggi-do, Korea

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Product Name: Sterilization Agent

GMDN Code No. : 18-005, Germicides, hydrogen peroxide

Model Name: RENO-SA10 or FINO-SA130

Classification : Class IIb (MDD 2007/47/EC, Annex IX Rule 15)

Conformity Assessment Route : Annex II, Excluding Section 4, MDD 2007/47/EC

Notified Body : SGS UK Ltd.

Unit 202B, World Parkway Weston-Super-Mare Somerset
BS 22 6WA United Kingdom

Standards applied : ISO13485:2016, EN ISO14971:2012, EN1041:2008,
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Product Name: Sterilization Agent

GMDN Code No. : 18-005, Germicides, hydrogen peroxide

Model Name: RENO-SA20 or FINO-SA20

Classification : Class IIb (MDD 2007/47/EC, Annex IX Rule 15)

Conformity Assessment Route : Annex II, Excluding Section 4, MDD 2007/47/EC

Notified Body : SGS UK Ltd.

Unit 202B, World Parkway Weston-Super-Mare Somerset
BS 22 6WA United Kingdom

Standards applied : ISO13485:2016, EN ISO14971:2012, EN1041:2008,
EN ISO 15223-1:2016, ISO14937:2009

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Product Name: Sterilization Agent

GMDN Code No. : 18-005, Germicides, hydrogen peroxide

Model Name: RENO-SA90

Classification : Class IIb (MDD 2007/47/EC, Annex IX Rule 15)

Conformity Assessment Route : Annex II, Excluding Section 4, MDD 2007/47/EC

Notified Body : SGS UK Ltd.

Unit 202B, World Parkway Weston-Super-Mare Somerset
BS 22 6WA United Kingdom

Standards applied : ISO13485:2016, EN ISO14971:2012, EN1041:2008,
EN ISO 15223-1:2016, ISO14937:2009

Manufacturers Registered Name : RENOSEM Co., Ltd.

EC Representative : MT-Promedt Consulting GmbH

Altenhofstrasse 80 66386 St. Ingbert, Germany



RENOSEM CO.,LTD.

Signature

A handwritten signature in blue ink, appearing to read 'Kwang-Sik Lee'.

PRESIDENT / K. S. LEE

Date: 04 Sep 2018

Kwang-Sik Lee/ CEO