health&beyond
优护优家

南通优护优家卫生用品有限公司
Nantong Health & Beyond Hygienic Products Inc.

EC Declaration of Conformity

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File Type: Technical File

Department	QC department
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Approved by	Michael Zhu
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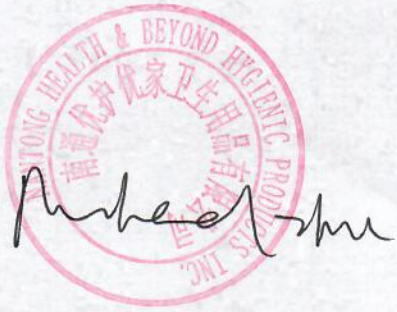

Revision history

Version	Change	Date	Revised by	Approved by
A/0	New Vision	2012.06.10	Kevin	Michael Zhu
A/1	Revise the information of the directive according to the new standard.	2015.06.02	William	Michael Zhu
A/2	1. Revise document format, prepared in accordance with the new template. 2. Revise the address information.	2015.06.25	William	Michael Zhu
A/3	Revise the validity of the certificate	2015.08.20	William	Michael Zhu
A/4	Replace the EU authorized representative	2019.05.26	Leila	Wei Wang
A/5	Update the version number of the coordination standard	2019.09.28	Leila	Michael Zhu
A/6	Modifying Notified Body	2019.12.16	Leila	Michael Zhu

3.1 Declaration of Conformity

Name and address of the firm :	**Nantong Health & beyond Hygienic Products Inc.** **No118, Yuxian Road, North-town Street, Rugao City** **Jiangsu Province, P. R. China.**
Name and address of the European Representative:	**Luxus Lebenswelt GmbH** **Kochstr. 1, 47877, Willich, Germany**
Medical device:	**Lubricating Jelly**
Model number:	**Lub0003,Lub0005,Lub0042,Lub0057,Lub0082,Lub0113**
UMDNS code:	**12401**
Classification:	**Class IIa, Rule V**

We herewith declare that the above mentioned products meet the transposition into national law,the provisions of the following EC Council Directives and Standards.All supporting documentations are retained under the premises of the manufacturer.

3.2 Directives

General applicable directives:

Medical Device Directives:COUNCL DIRECTIVES 93/42/EEC of 14 June 1993 concerning medical devices(MDD 93/42/EEC).Amended by DIRECTIVE 2007/47/EC of 5 September 2007.

Standard applied:

EN ISO 13485:2016,EN ISO 1041:2008, EN ISO 14971:2012, EN ISO 15223-1:2016
EN ISO 10993-1:2018, En ISO 10993-5:2009, EN ISO 10993-6:2016, EN ISO 10993-10:2013, EN ISO 10993-11:2018, EN ISO 10993-12:2012
En ISO 11737-1:2018, EN ISO 11737-2:2009, EN ISO 11137-1:2015, EN ISO 11137-2:2015
EN ISO 11607-1:2017 ,EN ISO 11607-2:2017, EN ISO 14155:2011
EN ISO 14644-1:2015, EN ISO 14644-2:2015, EN ISO 14698-1:2003,EN ISO 14698-2:2003
MEDDEV 2.12/1 Rev8, MEDDEV 2.12/2 Rev2, MEDDEV. 2.7.1 Rev.4, MDD.93/42/EEC

Notified Body:	**SGS Belgium NV, SGS House Noorderlaan 87 2030 Antwerp Belgium** **T+31（0）3545-48-48**
NB Identification NO.:	**1639**
Certificate(s):	**CN19/41072**
Expire date of the certificate:	**2023-08-28**
Name and Position	**Michael Zhu(General Manager)**

Michael Zhu

NANTONG HEALTH BEYOND HYGIENIC PRODUCTS INC. 南通健乐时用品有限公司

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QA supervisor