HOSPILITE
Operating Theater Lamp

DAI-ICHI SHOMEI CO., LTD.
32-26, Sakashita 1-chome, Itabashi-ku, Tokyo 174-0043, Japan
TEL : +81-3-3969-9223 FAX : +81-3-3969-9269

Declaration of Conformity

Product Identification	
Product Name	Model Number
AURORA ASTRO SURGICAL LIGHTS	AUA3, AUA33, AUA3S

Manufacturer		
Name of Company	Address and Contact Information	Representative
Dai-Ichi Shomei Co., Ltd.	32-26 Sakashita 1-Chome, Itabashi-Ku, Tokyo 174-0043 Japan p. 81-3-3969-9223 f. 81-3-3969-9269 dkk@hospilite.co.jp	Tomokazu Komine

Authorized Representative		
Name of Company	Address	Phone/Fax/E-mail
Skytron Europe BV	Floresstraat 52 8022 AD Zwolle Netherlands	p. 31(0) 384554040 f. 31(0) 384554030 sales@skytroneurope.com

Registration Information		
Notified Body ID#	CE Certificate Number	Date of CE Marking First Applied
N/A	N/A	April 24, 2017

Conformity Assessment	
Device Classification	Route to Compliance
Class I	The Council Directive 93/42/EEC with the amendments 2007/47/EC, concerning medical devices.

M.S.D.N: 0101180408 C.T.T.N.H.H CÔNG TY TRÁCH NHIỆM HỮU HẠN THƯƠNG MẠI HÙNG VƯƠNG Q. NAM TỪ LIÊM - T.P HÀ NỘI

SAO Y BẢN CHÍNH
Ngày 16 tháng 5 năm 2018

GIÁM ĐỐC
Trịnh Hà Thanh

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Standard Applied

To which this declaration relates is in conformity with the following standards:

EN 1041:2008
Information supplied by the manufacturer of medical devices

EN ISO 13485:2012
Medical devices — Quality management systems – Requirements for regulatory purposes
ISO 13485:2003

EN ISO 14971:2012
Medical devices — Application of risk management to medical devices
ISO 14971:2007

EN 60601-1:2006
Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1:2005

EN 60601-2-41:2009
Medical electrical equipment — Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis
IEC 60601-2-41:2009

EN 60601-1-2:2015
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-2:2014

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EN 60601-1-6:2010
Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-6:2010

EN 62366:2008
Medical devices - Application of usability engineering to medical devices
IEC 62366:2007

Dai-Ichi Shomei Co., Ltd. declares that the above mentioned product(s) meet the provision of the Council Directive 93/42/EEC for Medical Devices. All supporting documentation is retained at the premises of the manufacturer.

COMPANY REPRESENTATIVE Tomokazu Komine

TITLE President DATE August 24, 2017

SIGNATURE