AXELGAARD MANUFACTURING CO., LTD.

L4-08-4284 7/30/18

EC Declaration of Conformity

Manufacturer Name:	Axelgaard Manufacturing Co., Ltd.
Business Address:	520 Industrial Way Fallbrook, CA 92028-2244 USA
EU Representative	Axelgaard Manufacturing Co., Ltd.
Business Address:	Moegelhoej 2
Business Address:	DK-8520 Lystrup Denmark
Medical Devices:	**Thermal Reflector**, **Reference No. 3159, GMDN Code 16866**
Classification:	1
We Declare That:	The above noted devices conform to **Medical Device Directive 93/42/EEC** (as amended by Directive 2007/47/EC), and meet the requirements of Annex VII. The above noted devices meet the requirements of Directive 2011/65/EU on the Restrictions of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (as amended by **RoHS3 2015/863/EU**) and do not contain restricted substances. The above meet the requirements of **Decision 768/2008EC**, Annex II. Module A (A Common Framework for the Marketing of Products). The above noted devices are compliant to EC **REACH** regulation **1907/2006** as amended by **2017/999** (Regulation, Evaluation, Authorization and Restriction of Chemicals).
QMS Notified Body:	Intertek Testing Services NA Ltd.
QMS Certificate:	ISO 13485:2016 – 0077617-00
CE Reference:	CE-Mark Notification, Journal no.: 8711-888 Danish Medicines Agency conforms to Danish Medicines Agency directive 93/42/EEC (as amended by Directive 2007/47/EC).
Date:	30 July 2018
Signature:	Emily Adams, Director of Compliance and Regulatory Affairs