Attachment 1

Declaration of Conformity

Sterile Medical Devices–Article 11

CERTIFICATE NO.: DC29550 DATE: 23 Sep 2016

Legal Manufacturer Name and Address:	ArcRoyal, Virginia Road, Kells, Co. Meath.

Article 11 Declaration

ArcRoyal declares the medical device conforms to Article 11 of the Medical Device Directive 93/42/EEC by verifying the following:

It meets the requirements set out in Annex VII EC Declaration of Conformity of the Medical Device Directive

It meets the requirements set out in Annex V EC Declaration of Conformity (Product Quality Assurance) of the Medical Device Directive

These medical devices have been assembled and sterilized in compliance with the Annex V certification held by ArcRoyal, Presafe (Notified Body No. 0543) Certificate # 027, and the manufacturer's instructions where applicable.

The following Medical Device(s) comply:-

ArcRoyal Part No	Product Description	Work Order No. if applicable	Classification
AR-LHCB02	Light Handle Cover 2/pkt S	N/A	Class I
Classification of Medical Device (in accordance with Annex IX of the Medical Device Directive			

Signed pp Elaine Lynch 23 Sep 2016

Head of Quality or Designate - ArcRoyal