Aspen Surgical

Declaration of Conformity

Aspen Surgical Products, Inc.
6945 Southbelt Dr, SE
Caledonia, MI 49316 USA

We declare under our sole responsibility that the product group **Endoscopic Fog Inhibitor** specified below complies with the requirements of the Medical Device Directives of the European Union 93/42/EEC Annex II excluding Section 4.

Catalog Number	Description
DF-3100	Dr. Fog Solution with Sponge
DF-3100A	Dr. Fog Solution with Sponge
DF-3100B	Dr. Fog Solution with Sponge
DF-3120	Dr. Fog Treated Sponge
DF-3120B	Dr. Fog Treated Sponge
FC0013	Leonhard Lang/Fannin Anti-Fog

The Quality Management System Certification FM 570286 based on the harmonized standard EN ISO 13485:2012/AC:2012 and the EC Certification CE 612363 support this declaration. Notified Body is BSI, Kitemark Court, Davy Ave. Milton Keynes, UK MK5 8PP. Notified Body number is 0086.

We ensure and declare the above-mentioned product falls within the Class IIa, Rule 6, surgically invasive, transient use.

The legal address of our European Union representative:

Hill-Rom (UK) Limited
Clinitron House, Ashby Park
Ashby De La Zouch,
Leicestershire LE65 1JG
England

Caledonia, Michigan February 15, 2018
Place and Date of Issue

Megan Morrissey
Regulatory Affairs Manager
Aspen Surgical Products, Inc.