

**SURGICAL COMPANIES****FORM**

EU Declaration of Conformity

F4-03

Revision: 1

We

**BATRIK Medical Manufacturing Inc.**  
**850 Halpern**  
**Dorval, QC**  
**H9P 1G6, Canada**

<b>Part No.</b>	<b>Description</b>	<b>Pcs/sterile kit</b>	<b>UOM</b>
G.O.L.F.F.	Anti-Fog Solution	6 g + 1 sponge	20 sterile kits/box

Declare with sole responsibility, that the above-mentioned product has been assessed against Annex V of the European Council Directive 93/42/EEC of June 14, 1993, including the 2007/47/EEC amendments, Concerning Medical Devices (MDD) and meet the essential requirements of Annex I on this directive. These sterile products have been classified as class IIa as determined by the MDD, Annex IX, rule 6 (surgically invasive and transient).

The Quality Management System Certification US01/53984 based on the harmonized standard EN ISO 13485:2012 and the EC Certification US01/53983 support this declaration.

This assessment has been conducted by SGS United Kingdom Ltd. Systems & Services Certification: 202B, Worle Parkway, Weston-super-Mare, BS22 6WA, United Kingdom, notified Body number 0120.

We hereby appoint Advena Ltd., Pure Offices, Plato Close, Warwick CV34 6WE UK to act as European Authorized Representative as stipulated in the Medical Device Directive 93/42/EEC, including the 2007/47/EEC amendments.

Manufacturer's signature:



(Suzy Bairos, Vice President)

Date: June 6th, 2018