

According to the EC - Medical Device Directive 93/42/EEC

Manufacturer: SIS MEDICAL AG
Hungerbuelstrasse 12a
8500 Frauenfeld, Switzerland

Product Category: Injectors

Product Name: **Inflation Device**

Product Classification: Class I, based on Annex IX,
Rule 1

Conformity Assessment: Annex V

UM-DNS-Code: 15-284

GMDN-Code: 17541

We, SIS MEDICAL AG, hereby declare that the above mentioned product as listed has been designed and manufactured in conformity to the provisions of the European Directive 93/42/EEC as amended.

Notified Body: ecm, Bismarckstrasse 106, D-52066 Aachen, Germany
CE 0481

The product is supported by the following certificates:

EC Production Quality Assurance System Approval, Annex V of the Directive on Medical Devices

Certificate: Z/18/04207E

Date of issue: 2018-04-08

Expiry date: 2023-04-07



Dr. Erhard Hüsler, Head QA/RA
SIS MEDICAL AG



Date

Technical Specifications:

Reference number	96418	96345	96346	96463
Volume (cm ³)	40	25	25	14
Maximal Inflation Pressure (atm)	15	25	40	55

Product Family List:

Inflation Device

Article Numbers: 96418 (15 atm, 40 cc)
96345 (25 atm, 25 cc)
96346 (40 atm, 25 cc)
96463 (55 atm, 14 cc)