

ADVANCED STERILIZATION PRODUCTS

Division of Cilag GmbH International

a *Johnson & Johnson* company

DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

Manufacturer: Cilag GmbH International,
Advanced Sterilization Products
Gubelstrasse 34
6300 Zug, Switzerland

European Authorized Representative: Johnson & Johnson Medical GmbH
Robert-Koch-Str. 1,
22851 Norderstedt, Germany

Product: CIDEX® OPA Solution

Product Code(s)/Product Family Code and Description: 20391
CIDEX OPA Solution is a high level disinfectant for reprocessing heat sensitive medical devices.

Classification: Medical device classification IIb
(MDD 93/42/EEC, Annex IX, Rule 15)

GMDN Code: 47513

MDD TF Number: TF-20391

RoHS TF Number N/A

(If applicable):

We, Cilag GmbH International, Advanced Sterilization Products, hereby declare the above listed Medical Device(s) complies with Council Directive 93/42/EEC as amended by 2007/47/EC.

This declaration is made on the basis of:
EC Full Quality Assurance System Certificate No. G1 14 12 89139 002, issued by TÜV SÜD Product Service GmbH, with the Notified Body Number 0123, in accordance with Annex II excluding (4) of this Directive.

Signature Section



Monir El Azzouzi / Quality and Regulatory Compliance Manager /
Cilag International GmbH, Advanced Sterilization Products

June 9th, 2015

Date

PROPRIETARY AND CONFIDENTIAL

Gubelstrasse 34, 6300 Zug, Switzerland



protecting lives against infection