DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

Legal Manufacturer:	ASP International GmbH Zweigniederlassung Zug Gubelstrasse 34 6300 Zug, Switzerland
European Authorized Representative:	ASP, The Netherlands BV BIC 1, 5657 BX, Eindhoven, The Netherlands
Product:	CIDEX™ OPA Solution
Product Code(s)/Product Family Code and Description:	20391 CIDEX OPA Solution is used for high level disinfection of heat sensitive medical equipment used in the medical area
Classification:	Class IIb (MDD 93/42/EEC, Annex IX, Rule 15)
GMDN Code:	47631, Medical Device Disinfectant
MDD TF Number:	TF-20391
Start of CE-Marking:	4 March 2009
RoHS TF Number (If applicable):	Not Applicable
Physical Manufacturer:	Systagenix Wound Management Manufacturing Limited Gargrave, Skipton BD23 3RX United Kingdom

We, ASP International GmbH Zweigniederlassung Zug hereby declare that we are solely responsible for the above listed Medical Device(s), and the Medical Device(s) complies with Council Directive 93/42/EEC as amended by 2007/47/EC.

This Declaration of Conformity remains valid until a modification is necessitated by a conformity related change or the expiration of the EC Certificate.

The applied harmonized standards are listed with the Essential Requirements Checklist which resides in the Technical Files.

This declaration is made on the basis of: EC Quality System Certificate No. G1 105782 0001 Rev.01, issued by the TUV SUD Product Services GmbH Notified Body Number 0123, in accordance with Annex II of this Directive.

Notified Body TUV SUD Product Service GmbH Ridlerstrasse 65, D-80339 Munich, Germany

Sungyoon (Sunny) Rha/Director, Quality and Compliance/ Advanced Sterilization Products Zweigniederlassung Zug	22 MAR 2021 Date of Issue	Zug, Switzerland Place of Issue

Revision History

Revision	Summary of Changes	Release Date
A	Initial Release	03/10/2015
B	Revision to Declaration Text.	03/15/2016
C	Revision to add the place of issue, statement regarding standards applied and Start of CE-Marking. Added instructions and template for Declarations issued by ASP Cilag.	07/24/2017
D	Revision to update the GMDN Code.	9/26/2017
E	Removed Product Code 20690	9/20/2018
F	Technical File and ERC were revised to update to latest risk documents and additional efficacy testing was added.	02/07/2019
G	DoC was updated to new template and risk documentation in the Technical File was updated.	11/13/2019
H	Updated Legal Manufacturer with new legal name ASP International GmbH, and moved legacy J&J name to "trading as" name.	02/08/2020
J	Revised Legal Manufacturer Name and EC Certificate number, and updated Notified Body full name and address.	02/21/2020
K	New EC Certificate issued and revised in Technical File. Revision number 01 added to this DoC.	04/22/2020
L	Updated to new template and changed J&J to ASP European Authorized Representative. Replaced CIDEX® with CIDEX™ to align with Rebranded labeling.	03/02/2021
M	Updated Declaration of Conformity (DoC) template to include Physical Manufacturer information and revise DoC to include Physical Manufacturer information.	03/19/2021