EU DECLARATION OF CONFORMITY (MDR 2017/745)

Document No.:
DoC-MDR-M-20392
Revision: **C**

Legal Manufacturer: (Name and Address)	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 Name:	CIDEX™ OPA Solution Test Strips
Basic UDI-DI:	70105A1200000000000001294
Product Code(s)/Product Family Code and Description:	20392, CIDEX OPA Solution Test Strips, 60 Strips/Bottle 20393, CIDEX OPA Solution Test Strips, 15 Strips/Bottle
Intended Use/Purpose:	The CIDEX OPA Solution Test Strips are semi-quantitative chemical indicators for use in determining whether the concentration of ortho-phthalaldehyde, the active ingredient in CIDEX OPA Solution, is above or below the minimum effective concentration (MEC) established for CIDEX OPA Solution.
Classification:	Class I (Annex VIII, Rule 1)
GMDN Code:	46945
Technical Documentation (TD) Number:	TD-M-20392
Start of CE-Marking:	June 9, 1999
Physical Manufacturer:	Albert Browne LTD Chancery House Rayns Way Watermead Business Park Syston, Leicester LE7 1PF United Kingdom

We, ASP International GmbH Zweigniederlassung Zug, hereby declare that we are solely responsible for the above listed devices, and the devices comply with Medical Device Regulation (EU) 2017/745.

This EU Declaration of Conformity remains valid until a modification is necessitated by a conformity related change or the expiration of the EN ISO 13485 Certificate.

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Sunny Rha	20 APR 2021	Zug, Switzerland
Sungyoon (Sunny) Rha Director Quality & Compliance ASP Europe	Date of Issue	Place of Issue

	9 April 2021	Irvine, California, USA
Carolyn Shelton Vice President, Global Regulatory & Medical Affairs, Product Stewardship/ASP	Date of Issue	Place of Issue