

**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: 70105A120000000000001294

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

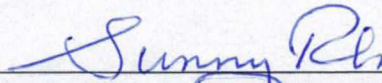
Physical Manufacturer: Albert Browne LTD
Chancery House
Rayns Way
Watermead Business Park
Syston, Leicester
LE7 1PF
United Kingdom

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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Sungyoon (Sunny) Rha
Director Quality & Compliance ASP Europe

20 APR 2021
Date of Issue

Zug, Switzerland
Place of Issue


Carolyn Shelton
Vice President, Global Regulatory & Medical Affairs, Product Stewardship/ASP

19 April 2021
Date of Issue

Irvine, California, USA
Place of Issue