



## DECLARATION OF CONFORMITY

to  
Directive 93/42/EEC concerning Medical Devices

Name of Product:	<b>Insertion System Class 1 Products</b>
Legal (labeled) Manufacturer Name:	Abbott Medical Optics Inc.
Manufacturer's Address:	1700 E. St. Andrew Place Santa Ana, California 92705 USA
EU Representative:	AMO Ireland Block B Liffey Valley Office Campus Quarryvale, Co Dublin Ireland
Contract Manufacturer:	RMS 8600 Evergreen Blvd. N Minneapolis, MN 55433-6036 USA

We, the undersigned, hereby declare on our own responsibility that the medical devices listed on this Declaration of Conformity meet all the provisions of the Directive 93/42/EEC concerning medical devices (including all subsequent amendments), which apply to them.

### ***Notified Body***

Not applicable, as Class I products (non sterile, no measuring function)

### ***Conformity Assessment Procedure***

Annex VII, MDD/93/42/EEC

### ***EC Certificate Number***

Not applicable, as Class I products

### ***Product Family Name / Number:***

UNFOLDER Emerald Series Handpiece, Models Emerald-AR, EmeraldT, EmeraldXL, SilverT, PSHST

This document is valid from the day of signature.



*O Biggs*  
Ophelia Biggs  
Associate Director, Regulatory Affairs

Date March 16, 2017

*DS*  
Dinamarie Stefani  
Director, Quality Assurance

Date March 16, 2017



**Duckworth & Kent Ltd.**  
titanium surgical instrument manufacturer

ISO9001:2008 and ISO13485:2003 Certified

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DUCKWORTH & KENT LTD.  
TERENCE HOUSE,  
7, MARQUIS BUSINESS CENTRE,  
ROYSTON ROAD,  
BALDOCK. HERTS.  
SG7 6XL, ENGLAND.

Declares that the following medical device is in conformity with the essential requirements and provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC.

DK7796 The Unfolder Platinum 1 Series Handpiece

Duckworth & Kent Limited Handpieces are manufactured from Titanium 6AL-4V and PEEK (Polyetheretherketone) and are classified as Class 1 devices in accordance with the Council Directive 93/42/EEC as amended by Directive 2007/47/EC.



Martin Lock  
Head of Quality Systems

Issue: 01

Date: 12.02.16

Chairman: T. A. Waldock  
Managing Director: J. Barker  
Directors: F. Waldock  
A. Waldock, B. Med. Sci. (Hons), B.M., B.S., F.R.C.Ophth., M.D.  
A. Waldock, M.Eng.

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