Duckworth & Kent Ltd
Titanium Reusable Ophthalmic Instrument Manufacturer
Terence House
7 Marquis Business Centre
Royston Road, Baldock
Hertfordshire, SG7 6XL
United Kingdom
+44 (0) 1462 893254
info@duckworth-and-kent.co.uk
www.duckworth-and-kent.com

ISO9001:2015 and ISO13485:2016 Certified

# EU DECLARATION OF CONFORMITY

Manufacturer:
Duckworth & Kent Ltd
Terence House
7 Marquis Business Centre
Royston Road
Baldock, Hertfordshire
SG7 6XL, United Kingdom

Authorised Representative:
Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Duckworth & Kent Ltd declares that the medical devices listed in Table 1 and described hereafter,

## Duckworth & Kent range of Non-Invasive Forceps

are in conformity with the essential requirements and provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC and as transposed into UK legislation (UK Medical Devices Regulations SI 2002 No. 618, as amended).

In accordance with Annex VII of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC and as transposed into UK legislation (UK Medical Devices Regulations SI 2002 No. 618, as amended),

### These devices are designated as Class I

Classification Route

These devices are all transient use, reusable, non-sterile, non-invasive medical devices.

The classification is determined under Annex IX, Rule 1.

This declaration is issued under the sole responsibility of Duckworth & Kent Ltd.

Martin Lock
Head of Regulatory Affairs

Date 14-MAY-2021
Issue 0
DCP 6469

**Table 1. Medical Devices covered under this Declaration of Conformity.**

| Forceps, Non-Invasive | |
|---|---|
| **REF** | **Device Title** |
| 2-100 | Notched Forceps |
| 2-100-1E | Notched Forceps |
| 2-100E | Notched Forceps |
| 2-101E | Notched Forceps |
| 2-103E | Notched Forceps |
| 2-104E | Notched Forceps |
| 2-130E | Notched Forceps |
| 2-195 | Cilia Forceps |
| 2-195-1 | Cilia Forceps |
| 2-196 | Cilia Forceps |
| 2-200E | Notched Forceps |
| 2-2195E | Cilia Forceps |
| 2-2-833S | Locking Segment Forceps |
| 2-285E | DMEK Forceps |
| 2-287E | DMEK Forceps |
| 2-500 | Tying Forceps |
| 2-500-1E | Tying Forceps |
| 2-500-2E | Tying Forceps |
| 2-500E | Tying Forceps |
| 2-501E | Tying Forceps |
| 2-502E | Suture Forceps |
| 2-504E | Tying Forceps |
| 2-504ER8 | Tying Forceps |
| 2-505E | Tying Forceps |
| 2-505ER8 | Tying Forceps |
| 2-510-1E | Utility Forceps |
| 2-520E | Tying Forceps |
| 2-522E | Tying Forceps |
| 2-524-1E | Tying Forceps |
| 2-524E | Tying Forceps |
| 2-526E | Tying Forceps |
| 2-527E | Tying Forceps |
| 2-529-1ER8 | Tying Forceps |
| 2-529E | Tying Forceps |
| 2-640 | Lid Clamp |
| 2-729-1 | Main Body Loading Forceps |
| 2-729-3 | Shuttle Forceps |
| 2-731 | Fixation Station Forceps |
| 2-765-1 | IOL Forceps |
| 2-770E | ICL Forceps |
| 2-774-1E | IOL Forceps |
| 2-795E | Flap Forceps |
| 2-832E | Cannula Forceps |
| 2-896-2 | ICL Forceps |
| 2-896-3 | ICL Forceps |
| 2-900E | Plain Forceps |
| 6-675 | Flushing Adaptor |
| 6-675-1 | Flushing Adaptor |
| 6-676 | Squeeze Handle |

| Forceps, Non-Invasive | |
|---|---|
| **REF** | **Device Title** |
| 6-805 | Utility Clamp |
| 8-648 | Kurakazu Cutter Assister |
| DK7710E | IOL Forceps |
| DK7717E | IOL Forceps |
| DK7726 | IOL Forceps |

**Table 2. Relevant standards and common specifications.**

| Applicable Standards | |
|---|---|
| **Standard Number** | **Title** |
| EN 1041:2008 | Information supplied by the manufacturer of medical devices |
| EN ISO 10993-1:2009 | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009) EN ISO 10993-1:2009/AC:2010 |
| EN ISO 13485:2016 | Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2018 |
| EN ISO 14971:2012 | Medical Devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01) |
| EN ISO 15223-1:2016 | Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03) |
| EN ISO 17664:2017 | Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices (ISO 17664:2017) |
| EN 20594-1:1993+A1:1997 | Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements (ISO 594-1:1986) |
| EN 62366-1:2015+A1:2020 | Medical devices - Part 1: Application of usability engineering to medical devices |
| 93/42/EEC | Council Directive concerning medical devices |
| 2007/47/EC | Council Directive amending 93/42/EEC |
| SI 2002 No. 618 | Medical Devices Regulations (UK) |
| MEDDEV 2.7/1 rev.4 June 2016 | Clinical evaluation: A guide for manufacturers and notified bodies |
| MEDDEV 2.12/1 rev.8 Jan 2013 | Guidelines on a medical device's vigilance system |

Duckworth & Kent Ltd
Titanium Reusable Ophthalmic Instrument Manufacturer
Terence House
7 Marquis Business Centre
Royston Road, Baldock
Hertfordshire, SG7 6XL
United Kingdom
+44 (0) 1462 893254
Info@duckworth-and-kent.co.uk
www.duckworth-and-kent.com

ISO13485:2016 Certified

# ADDENDUM TO THE ORIGINAL DECLARATION OF CONFORMITY

Per 31 January 2023, the address of our EU Authorised Representative as listed on the original Declaration of Conformity has changed

Old Address
Authorised Representative: Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

New Address
Authorised Representative: Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

Martin Lock
Head of Regulatory Affairs

25/01/23
Date