Duckworth & Kent Ltd
Titanium Reusable Ophthalmic Instrument Manufacturer
Terence House
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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 Invasive Hooks & Probes

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, invasive medical devices.

The classification is determined under Annex IX, Rule 5.

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

Martin Lock
Head of Regulatory Affairs

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

Hooks & Probes, Invasive	
REF	**Device Title**
6-069	Nucleus Chopper
6-071	Nucleus Chopper
6-072-1	Nucleus Chopper
6-074-1	Nucleus Chopper
6-074-2	Nucleus Chopper
6-075	Nucleus Chopper
6-075-1	Nucleus Chopper
6-076	Nucleus Chopper
6-079	Nucleus Chopper
6-079-1	Nucleus Chopper
6-080	Nucleus Chopper
6-080-2	Nucleus Chopper
6-080-3	Nucleus Chopper
6-080-4	Nucleus Chopper
6-081	Nucleus Chopper
6-081-3	Nucleus Chopper
6-083	Nucleus Chopper
6-083-1	Nucleus Chopper
6-083-5	Nucleus Chopper
6-085	Nucleus Chopper
6-085-1	Nucleus Chopper
6-085-2	Nucleus Chopper
6-085-3	Nucleus Chopper
6-085-6	Nucleus Chopper
6-085-8	Nucleus Chopper
6-086	Nucleus Chopper
6-086-1	Nucleus Chopper
6-086-4	Hook
6-086-5	Nucleus Chopper
6-086-6	Nucleus Chopper
6-086-7	Hook
6-087	Nucleus Chopper
6-087-1	Nucleus Chopper
6-090	Nucleus Divider
6-090-3	Nucleus Divider
6-090-6	Nucleus Divider
6-090-7	Nucleus Divider
6-090-8	Nucleus Divider
6-093	Nucleus Chopper
6-095	Nucleus Sustainer
6-098-3	Spatula
6-099	Spatula
6-099-1	Spatula
6-099-2	Spatula
6-099-3	Spatula
6-099-4	Spatula
6-100	Spatula
6-101	Spatula
6-102	Spatula

Hooks & Probes, Invasive	
REF	**Device Title**
6-105-1	Spatula
6-107	Spatula
6-130	Iris Retractor
6-140	Cataract Support
6-180	Lacrimal Dilator
6-180-1	Lacrimal Dilator
6-181	Lacrimal Dilator
6-194-2	Shuttle
6-245	Sinskey Hook
6-249	Sinskey Hook
6-250	Sinskey Hook
6-250-1	DMEK Hook
6-250-2	DMEK Hook
6-251	Sinskey Hook
6-256	DMEK Scraper
6-257	DMEK Scraper
6-258	DMEK Hook
6-400	IOL Manipulator
6-400-1	IOL Manipulator
6-417	IOL Manipulator
6-418	IOL Manipulator
6-418-1	IOL Manipulator
6-450	IOL Manipulator
6-460	IOL Manipulator
6-467	IOL Manipulator
6-469	IOL Manipulator
6-469-1	IOL Manipulator
6-470	Nucleus Rotator
6-472	Nucleus Manipulator
6-472-1	Nucleus Manipulator
6-476	Nucleus Rotator
6-479	ICL Manipulator
6-481	ICL Manipulator
6-482	ICL Manipulator
6-491-2	Nucleus Rotator
6-491-3	Nucleus Rotator
6-494	Nucleus Rotator
6-495	Nucleus Rotator
6-496	Nucleus Rotator
6-496-1	Nucleus Rotator
6-496-2	Nucleus Rotator
6-500	Hook
6-510	Capsule Polisher
6-610	Lens Loop
6-630	Nucleus Expressor
6-635-4	Scleral Depressor
6-649	Fixation Station
6-651	Fixation Station
6-652	Fixation Station
6-656	Lacrimal Probe
6-656-1	Lacrimal Probe
6-656-2	Lacrimal Probe

Hooks & Probes, Invasive	
REF	**Device Title**
6-656-3	Lacrimal Probe
6-656-4	Lacrimal Probe
6-656-5	Lacrimal Probe
6-835	SMILE Dissector
6-836	SMILE Dissector
6-836-1	SMILE Dissector
6-836-2	SMILE Dissector
6-837	SMILE Hook
6-839	SMILE Dissector
6-848	Femto Spatula
6-855	Femto Spatula
6-855-1	Femto Spatula
6-856	Femto Spatula
6-866	Epithelial Separator
6-870	LASIK Spatula
6-912	Membrane Spatula
DO6-41	Artisan Manipulator Standard - Straight
OF115	Artiflex Manipulator

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 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

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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