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 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, 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.

Forceps, Invasive	
REF	**Device Title**
2-110	Toothed Forceps
2-110-1E	Toothed Forceps
2-110-3E	Toothed Forceps
2-110E	Toothed Forceps
2-111E	Toothed Forceps
2-114E	Toothed Forceps
2-114ER8	Toothed Forceps
2-116E	Toothed Forceps
2-118E	Toothed Forceps
2-132	Toothed Forceps
2-132E	Toothed Forceps
2-135E	Toothed Forceps
2-135ER8	Toothed Forceps
2-144E	Toothed Forceps
2-167E	Conjunctival Forceps
2-170E	Toothed Forceps
2-185	Toothed Forceps
2-214E	Toothed Forceps
2-215E	Toothed Forceps
2-2-706GR	Capsulorhexis Forceps
2-2-716G-8RS	Capsulorhexis Forceps
2-500-4E	Conjunctival Forceps
2-501-2E	Tying Forceps
2-503E	Conjunctival Forceps
2-686	Conjunctival Clamp
2-687	Conjunctival Clamp
2-695	IOL Forceps
2-700	IOL Forceps
2-706G-1E	Capsulorhexis Forceps
2-706G-1RE	Capsulorhexis Forceps
2-706GE	Capsulorhexis Forceps
2-706GRE	Capsulorhexis Forceps
2-712-3ER8	Capsulorhexis Forceps
2-712-4ER8	Capsulorhexis Forceps
2-714-3ER8	Capsulorhexis Forceps
2-716G-10E	Capsulorhexis Forceps
2-716G-10RE	Capsulorhexis Forceps
2-716G-8E	Capsulorhexis Forceps
2-716G-8RE	Capsulorhexis Forceps
2-716G-8RSE	Capsulorhexis Forceps
2-716G-8SE	Capsulorhexis Forceps
2-716G-9E	Capsulorhexis Forceps
2-716G-9RE	Capsulorhexis Forceps
2-716G-9RSE	Capsulorhexis Forceps
2-716G-9SE	Capsulorhexis Forceps
2-716GE	Capsulorhexis Forceps
2-716GE-1	Capsulorhexis Forceps
2-716GE-1S	Capsulorhexis Forceps
2-716GE-2	Capsulorhexis Forceps

Forceps, Invasive	
REF	**Device Title**
2-716GE-3	Capsulorhexis Forceps
2-716GER8	Capsulorhexis Forceps
2-716GER8-1	Capsulorhexis Forceps
2-716GER8-1S	Capsulorhexis Forceps
2-716GER8-2	Capsulorhexis Forceps
2-716GER8-3	Capsulorhexis Forceps
2-716GN-2E	Capsulorhexis Forceps
2-716GN-3E	Capsulorhexis Forceps
2-716GN-4	Capsulorhexis Forceps
2-716GN-4E	Capsulorhexis Forceps
2-716GN-5E	Capsulorhexis Forceps
2-716GNE	Capsulorhexis Forceps
2-716GNR8-2E	Capsulorhexis Forceps
2-716GNR8-3	Capsulorhexis Forceps
2-716GNR8-3E	Capsulorhexis Forceps
2-716GNR8-4E	Capsulorhexis Forceps
2-716GNR8-5	Capsulorhexis Forceps
2-716GNR8-5E	Capsulorhexis Forceps
2-716GNR8-6E	Capsulorhexis Forceps
2-716GNR8E	Capsulorhexis Forceps
2-716GW	Capsulorhexis Forceps
2-716GW-2	Capsulorhexis Forceps
2-716GWR8-2	Capsulorhexis Forceps
2-718-3E	Capsulorhexis Forceps
2-719-3E	Capsulorhexis Forceps
2-719-4E	Capsulorhexis Forceps
2-787-1E	DMEK Forceps
2-796E	Nucleus Forceps
2-802E	Nucleus Cracker
2-803E	Nucleus Cracker
2-815E	Prechopper Forceps
2-817-1E	Prechopper Forceps
2-817E	Prechopper Forceps
2-818E	Prechopper Forceps
2-820-1E	Prechopper Forceps
2-820E	Prechopper Forceps
2-821E	Prechopper Forceps
2-835E	SMILE Forceps
2-836E	SMILE Forceps
2-837	SMILE Forceps
2-838	DMEK Forceps
2-839	SMILE Forceps
2-847-4	Capsulorhexis Forceps
2-877	Vitreoretinal Forceps
2-877N	Vitreoretinal Forceps Head
2-878-1	Vitreoretinal Forceps
2-878-1N	Vitreoretinal Forceps Head
DK7740E	IOL Forceps
DO2-40	Artisan Enclavation Forceps
DO2-70	Artisan Implantation Forceps Refractive - Long
DO2-72	Artisan Implantation Forceps Refractive - Short
DO2-74	Artisan Implantation Forceps - Standard

Forceps, Invasive	
REF	**Device Title**
OF105	Artiflex Holding Forceps Curved Left
OF106	Artiflex Holding Forceps Curved Right
P5307A	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 1707:1996	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings
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

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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

M Lock ..... 25/01/23 .....

Martin Lock
Head of Regulatory Affairs

Date