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
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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 Irrigation & Aspiration devices

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 Device Regulations 2002 S.I. No 618, as amended).

In accordance with Annex II (excluding section 4) of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC,

These devices are designated as Class IIa

Notified Body:
SGS Belgium NV (NB 1639)
Noorderlaan 87
2514 Antwerpen
Belgium

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.

Irrigation & Aspiration IIa, Invasive			
REF	**Device Title**	**Description**	**Intended Use**
8-601-1	Cannula	Hydrodissection cannula	Intended to supply fluid into the capsule of the eye to release the nucleus from the capsular bag
8-601-2	Cannula	Multipurpose cannula	Intended to supply fluid into the capsule of the eye to release the nucleus from the capsular bag, also for removal of air, fluid and liquefied cortex from the eye
8-602	Cannula	Flat tipped cannula	Intended to supply fluid into the capsule of the eye to release the nucleus from the capsular bag
8-603	Cannula	Capsule polishing cannula	Intended to remove fluid, viscoelastic and small pieces of tissue from the anterior of the eye
8-605	Cannula	Air injection cannula	Intended to supply air into the anterior chamber of the eye
8-616	Cannula	Infusion cannula	Intended to supply fluid into the eye to maintain intraocular pressure during a surgical procedure
8-650	Irrigation Handpiece	Irrigation handpiece	Intended to supply fluid into the eye to maintain intraocular pressure during a surgical procedure
8-652	Irrigation Handpiece	Irrigation handpiece	Intended to supply fluid into the eye to maintain intraocular pressure during a surgical procedure
8-652-1	Irrigation Handpiece	Irrigation handpiece	Intended to supply fluid into the eye to maintain intraocular pressure during a surgical procedure
8-655	Aspiration Handpiece	Aspiration handpiece	Intended to remove fluid, viscoelastic and small pieces of tissue from the anterior of the eye
8-655-2	Aspiration Handpiece	Aspiration handpiece	Intended to remove fluid, viscoelastic and small pieces of tissue from the anterior of the eye
8-657	Aspiration Handpiece	Aspiration handpiece	Intended to remove fluid, viscoelastic and small pieces of tissue from the anterior of the eye
8-730	I/A Tip	Aspiration tip	Intended to remove fluid, viscoelastic and small pieces of tissue from the anterior of the eye
8-731	I/A Tip	Aspiration tip	Intended to remove fluid, viscoelastic and small pieces of tissue from the anterior of the eye
8-731-1	I/A Tip	Aspiration tip	Intended to remove fluid, viscoelastic and small pieces of tissue from the anterior of the eye
8-731-3	I/A Tip	Aspiration tip	Intended to remove fluid, viscoelastic and small pieces of tissue from the anterior of the eye
8-731-4	I/A Tip	Aspiration tip	Intended to remove fluid, viscoelastic and small pieces of tissue from the anterior of the eye
8-732	I/A Tip	Aspiration tip	Intended to remove fluid, viscoelastic and small pieces of tissue from the anterior of the eye

Irrigation & Aspiration IIa, Invasive			
REF	**Device Title**	**Description**	**Intended Use**
8-732-1	I/A Tip	Aspiration tip	Intended to remove fluid, viscoelastic and small pieces of tissue from the anterior of the eye
8-732-3	I/A Tip	Aspiration tip	Intended to remove fluid, viscoelastic and small pieces of tissue from the anterior of the eye
8-732-4	I/A Tip	Aspiration tip	Intended to remove fluid, viscoelastic and small pieces of tissue from the anterior of the eye

Table 2. Relevant standards and common specifications.

Applicable Standards	
Standard Number	**Title**
BS EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. *This standard is applied in full*
BS EN ISO 13485:2016+A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes. *This standard is applied in full*
BS EN ISO 14971:2019+A11:2021	Medical Devices - Application of risk management to medical devices. *This standard is applied in full*
BS EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements. *This standard is applied in full*
BS EN ISO 17664:2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices. Part 1: Critical and semi-critical medical devices. *This standard is applied in full*
BS EN ISO 20417:2021	Medical devices – Information to be supplied by the manufacturer. *This standard is applied in full*
BS EN ISO 80369-1:2018	Small-bore connectors for liquids and gases in healthcare applications. Part 1: General requirements. *This standard is applied in full*
BS EN ISO 80369-7:2021	Small-bore connectors for liquids and gases in healthcare applications. Part 7: Connectors for intravascular or hypodermic applications. *This standard is applied in full*
93/42/EEC	Council Directive concerning medical devices *This standard is applied in full*
2007/47/EC	Council Directive amending 93/42/EEC *This standard is applied in full*
MEDDEV 2.1/1 rev April 1994	Guidelines relating to the application of: The council directive 90/385/EEC on active implantable medical devices, The council directive 93/42/EEC on medical devices. *This guidance document is applied in full*
MEDDEV 2.4/1 rev 9 June 2010	Guidelines relating to the application of the council directive 93/42/EEC on medical devices. *This guidance document is applied in full*
MEDDEV 2.7/1 rev.4 June 2016	Clinical evaluation: A guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC. *This guidance document is applied in full*
MEDDEV 2.12/1 rev.8 Jan 2013	Guidelines on a medical device's vigilance system. *This guidance document is applied in full*
MEDDEV 2.12/2 rev 2 Jan 2012	Guidelines on medical devices, Post market clinical follow-up studies. *This guidance document is applied in full*

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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