



**Duckworth & Kent Ltd**

Titanium Reusable Ophthalmic Instrument Manufacturer

+44 (0) 1462 893254

@ Info@duckworth-and-kent.co.uk



www.duckworth-and-kent.com

Terence House  
7 Marquis Business Centre  
Royston Road, Baldock  
Hertfordshire, SG7 6XL  
United Kingdom

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 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, non-invasive medical devices.

The classification is determined under Annex IX, Rule 2.

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 Ila, Non-Invasive			
REF	Device Title	Description	Intended Use
8-711-1N	I/A Handpiece	I/A handpiece with irrigation Luer fitting	Intended to supply fluid into the eye to maintain intraocular pressure during a surgical procedure whilst through a secondary tube to remove fluid, viscoelastic and small pieces of tissue from the anterior of the eye
8-711-1NL	I/A Handpiece	I/A handpiece with irrigation Luer lock fitting	Intended to supply fluid into the eye to maintain intraocular pressure during a surgical procedure whilst through a secondary tube to remove fluid, viscoelastic and small pieces of tissue from the anterior of the eye
8-711N	I/A Handpiece	I/A handpiece with irrigation Luer fitting	Intended to supply fluid into the eye to maintain intraocular pressure during a surgical procedure whilst through a secondary tube to remove fluid, viscoelastic and small pieces of tissue from the anterior of the eye
8-711NL	I/A Handpiece	I/A handpiece with irrigation Luer lock fitting	Intended to supply fluid into the eye to maintain intraocular pressure during a surgical procedure whilst through a secondary tube to remove fluid, viscoelastic and small pieces of tissue from the anterior of the eye
8-720	Cannula Handle	Cannula handle	Intended to fit onto a standard cannula Luer fitting for either the irrigation to or aspiration of fluids from 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. <i>This standard is applied in full</i>
BS EN ISO 13485:2016+A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes. <i>This standard is applied in full</i>
BS EN ISO 14971:2019+A11:2021	Medical Devices - Application of risk management to medical devices. <i>This standard is applied in full</i>
BS EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements. <i>This standard is applied in full</i>
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. <i>This standard is applied in full</i>
BS EN ISO 20417:2021	Medical devices – Information to be supplied by the manufacturer. <i>This standard is applied in full</i>
BS EN ISO 80369-1:2018	Small-bore connectors for liquids and gases in healthcare applications. Part 1: General requirements. <i>This standard is applied in full</i>
BS EN ISO 80369-7:2021	Small-bore connectors for liquids and gases in healthcare applications. Part 7: Connectors for intravascular or hypodermic applications. <i>This standard is applied in full</i>
93/42/EEC	Council Directive concerning medical devices <i>This standard is applied in full</i>
2007/47/EC	Council Directive amending 93/42/EEC <i>This standard is applied in full</i>
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. <i>This guidance document is applied in full</i>
MEDDEV 2.4/1 rev 9 June 2010	Guidelines relating to the application of the council directive 93/42/EEC on medical devices. <i>This guidance document is applied in full</i>
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. <i>This guidance document is applied in full</i>
MEDDEV 2.12/1 rev.8 Jan 2013	Guidelines on a medical device's vigilance system. <i>This guidance document is applied in full</i>
MEDDEV 2.12/2 rev 2 Jan 2012	Guidelines on medical devices, Post market clinical follow-up studies. <i>This guidance document is applied in full</i>



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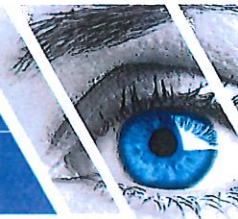


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## ADDENDUM TO THE ORIGINAL DECLARATION OF CONFORMITY

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