



## 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
8-609	Luer Lock	Luer lock fitting	Intended to fit onto a standard Luer fitting for either the irrigation to or aspiration of fluids from the eye
8-609-1	Luer Lock	Luer lock fitting	Intended to fit onto a standard Luer fitting for either the irrigation to or aspiration of fluids from the eye
8-609-2	Luer Lock	Luer lock fitting	Intended to fit onto a standard Luer fitting for either the irrigation to or aspiration of fluids from the eye
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
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)
ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
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
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



**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 .....

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Date