



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 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, non-invasive medical devices.

The classification is determined under Annex IX, Rule 1.

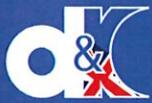
This declaration is issued under the sole responsibility of Duckworth & Kent Ltd.

Martin Lock
Head of Regulatory Affairs



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

Forceps, Non-Invasive	
REF	Device Title
2-100	Notched Forceps
2-100-1E	Notched Forceps
2-100E	Notched Forceps
2-101E	Notched Forceps
2-103E	Notched Forceps
2-104E	Notched Forceps
2-130E	Notched Forceps
2-195	Cilia Forceps
2-195-1	Cilia Forceps
2-196	Cilia Forceps
2-200E	Notched Forceps
2-2195E	Cilia Forceps
2-2-833S	Locking Segment Forceps
2-285E	DMEK Forceps
2-287E	DMEK Forceps
2-500	Tying Forceps
2-500-1E	Tying Forceps
2-500-2E	Tying Forceps
2-500E	Tying Forceps
2-501E	Tying Forceps
2-502E	Suture Forceps
2-504E	Tying Forceps
2-504ER8	Tying Forceps
2-505E	Tying Forceps
2-505ER8	Tying Forceps
2-510-1E	Utility Forceps
2-520E	Tying Forceps
2-522E	Tying Forceps
2-524-1E	Tying Forceps
2-524E	Tying Forceps
2-526E	Tying Forceps
2-527E	Tying Forceps
2-529-1ER8	Tying Forceps
2-529E	Tying Forceps
2-640	Lid Clamp
2-729-1	Main Body Loading Forceps
2-729-3	Shuttle Forceps
2-731	Fixation Station Forceps
2-765-1	IOL Forceps
2-770E	ICL Forceps
2-774-1E	IOL Forceps
2-795E	Flap Forceps
2-832E	Cannula Forceps
2-896-2	ICL Forceps
2-896-3	ICL Forceps
2-900E	Plain Forceps
6-675	Flushing Adaptor
6-675-1	Flushing Adaptor
6-676	Squeeze Handle



Forceps, Non-Invasive	
REF	Device Title
6-805	Utility Clamp
8-648	Kurakazu Cutter Assister
DK7710E	IOL Forceps
DK7717E	IOL Forceps
DK7726	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 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



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