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 Non-Invasive Measuring Devices

are in conformity with the essential requirements and provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC.

In accordance with Annex V (Metrological aspects only) of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC,

**These devices are designated as Class I Measuring**

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 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.**

| Measuring Devices Im, Non-Invasive | | | |
|---|---|---|---|
| **REF** | **Device Title** | **Description** | **Intended Use** |
| 6-626 | Muscle Hook | Resection muscle hook | Intended to support the extra ocular muscle, enabling insertion of sutures during resection of the muscle. |
| 6-626-1 | Muscle Hook | Resection muscle hook | Intended to support the extra ocular muscle, enabling insertion of sutures during resection of the muscle. |

**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) |
| 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 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 |

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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