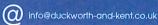
Terence House 7 Marquis Business Centre Royston Road, Baldock Hertfordshire, SG7 6XL United Kingdom







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 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, 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

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





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

| Measuring Devies Im, Invasive | | | |
|-------------------------------|------------------|------------------|---|
| REF | Device Title | Description | Intended Use |
| 6-182-2 | Lacrimal Dilator | Lacrimal dilator | Intended to dilate the Lacrimal puncta and therefore determine the size of punctum plug to be fitted. |

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 | | |

Date 14-MAY-2021

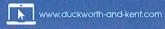
Issue 0 DCP 6481

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









ISO13485:2016 Certified

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

Date 25-JAN-2023

Issue 0 DCP 6630