



## 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 Hooks & Probes**

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.**

Hooks & Probes, Non-Invasive	
REF	Device Title
6-615	Scleral Depressor
6-615-1	Scleral Depressor
6-620	Muscle Hook
6-625	Muscle Hook
6-628	Lid Retractor
6-629	Lid Retractor
6-635-2	Scleral Depressor
6-635-3	Scleral Depressor
8-011	Actuation Tool

**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 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