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









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 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

Date 14-MAY-2021

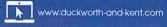
Issue 0 DCP 6469

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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	

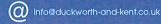
Table 2. Relevant standards and common specifications.

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		

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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

Date 25-JAN-2023

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