



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 Speculum

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.

Speculum, Non-Invasive	
REF	Device Title
6-600	Scleral Support Rings
6-664	Eye Shield
6-665	Eye Shield
6-667	Eye Shield
6-667-2	Eye Shield
6-667-3	Eye Shield
6-667-4	Eye Shield
6-667-6	Eye Shield
6-667-7	Eye Shield
6-700	Keratometer
9-550	Speculum
9-551	Speculum
9-552	Speculum
9-552F	Speculum
9-555	Speculum
9-556	Speculum
9-557	Speculum
9-559	Speculum
9-560	Speculum
9-560-1	Speculum
9-561	Speculum
9-566	Speculum
9-572	Speculum
9-573	Speculum
9-573-1	Speculum
9-574	Speculum
9-574-1	Speculum
9-576	Speculum
9-576-4	Speculum
9-576-5	Speculum
9-577-3	Speculum
9-577-4	Speculum
9-578	Speculum
9-578-2	Speculum
9-578-8	Speculum
9-579	Speculum
9-579-2	Speculum
9-579-6	Speculum
9-581F	Speculum
9-583	Speculum
9-585	Speculum
9-588	Speculum
9-588-1	Speculum
9-588-2	Speculum
9-588-3	Speculum
9-589	Speculum
9-590	Speculum
9-591	Speculum
9-592	Speculum



Speculum, Non-Invasive	
REF	Device Title
9-595	Speculum
9-597	Speculum
9-597-1	Speculum
9-598-2	Speculum
9-599	Speculum
9-599-1	Speculum

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