Duckworth & Kent Ltd
Titanium Reusable Ophthalmic Instrument Manufacturer
Terence House
7 Marquis Business Centre
Royston Road, Baldock
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ISO9001:2015 and ISO13485:2016 Certified

EU IZJAVA O SUKLADNOSTI

Proizvođač:

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

Ovlašteni predstavnik:

Emergo Europe
Princessegracht 20
2514 AP The Hague
The Netherlands

Duckworth & Kent Ltd izjavljuje da medicinski uređaji navedeni u Tabeli 1 i opisani u nastavku,

Uređaji za mjerenje Duckworth & Kent s invazivnom tehnologijom

u skladu su s osnovnim zahtjevima i odredbama Direktive Vijeća 93/42/EEZ, kako je izmijenjena Direktivom 2007/47/EZ.

U skladu s Prilogom V. (samo metrološki aspekti) Direktive Vijeća 93/42/EEZ, kako je izmijenjena Direktivom 2007/47/EZ,

Ovi su uređaji označeni kao Razred I Mjerenje

Obaviješteno tijelo:

SGS Belgium NV (NB 1639)
Noorderlaan 87
2514 Antwerpen
Belgium

Staza klasifikacije

Svi su ti uređaji namijenjeni povremenoj uporabi, ponovnoj uporabi, nesterilni su i invazivni medicinski uređaji.

Klasifikacija se određuje u skladu s pravilom 5 Priloga IX.

Ova izjava izdana je pod isključivom odgovornošću društva Duckworth & Kent Ltd.

Martin Lock
Voditelj regulatornih poslova

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Tabela 1. Medicinski uređaji obuhvaćeni ovom Izjavom o sukladnosti.

Mjerenje Im, invazivno			
REF	**Naziv uređaja**	**Opis**	**Namjena**
6-182-2	Dilatator za suzovod	Suzni dilatator	Namijenjen je dilataciji suznih točaka, stoga se njime određuje veličina čepa koji treba postaviti.

Tabela 2. Relevantne norme i zajedničke specifikacije.

Primjenjive norme	
Broj norme	**Naziv**
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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DODATAK IZVORNOJ IZJAVI O SUKLADNOSTI

Dana 31.siječnja 2023.adresa našeg ovlaštenog predstavnika za EU navedena u izvornoj Izjavi o sukladnosti se promijenila

Stara adresa
Ovlašteni predstavnik:

Emergo Europe
Princessegracht 20
2514 AP The Hague
The Netherlands

Nova adresa
Ovlašteni predstavnik:

Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

Martin Lock
Voditelj regulatornih poslova

25|01|23
Datum