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

EU IZJAVA O SKLADNOSTI

Proizvajalec:

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

Pooblaščeni predstavnik:

Emergo Evropa
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Podjetje Duckworth & Kent Ltd izjavlja, da so medicinske naprave, navedene v tabeli 1 in opisane v nadaljevanju,

Duckworth & Kent paleta invazivnih merilnih naprav

v skladu z bistvenimi zahtevami in določbami Direktive Sveta 93/42/EGS, kakor je bila spremenjena z Direktivo 2007/47/ES,

v skladu s Prilogo V (le Meroslovni vidiki) Direktive Sveta 93/42/EGS, kakor je bila spremenjena z Direktivo 2007/47/ES,

Te naprave so označene kot razred I Merilne

Priglašeni organ:

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

Postopek razvrstitve

Vse te naprave so invazivne nesterilne medicinske naprave, namenjene prehodni in ponovni uporabi.

Razvrstitev se določi v skladu s členom 5 Priloge IX.

Ta izjava je izdana pod izključno odgovornostjo podjetja Duckworth & Kent Ltd.

Martin Lock
Vodja oddelka za regulativne zadeve

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Tabela 1. Medicinske naprave, ki jih zajema ta izjava o skladnosti.

Merilne naprave Im, invazivne			
REF	**Naziv naprave**	**Opis**	**Namen uporabe**
6-182-2	Lakrimalni dilatator	Lakrimalni dilator	Namenjen za razširjanje solzovodov, kar pomaga določati velikost čepa, ki se ga namesti.

Tabela 2. Zadevni standardi in skupne specifikacije.

Veljavni standardi	
Številka standarda	**Naslov**
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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DODATEK K IZVIRNIKU
IZJAVA O SKLADNOSTI

Od 31. januarja 2023 se je spremenil naslov našega pooblaščenega predstavnika EU, ki je naveden v prvotni izjavi o skladnosti

Stari naslov
Pooblaščeni predstavnik: Emergo Evropa
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Novi naslov
Pooblaščeni predstavnik: Emergo Evropa
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

M Lock ..... 25|01|23 .....

Martin Lock
Vodja oddelka za regulativne zadeve

Datum