Declaration of EC Conformity



Manufacturer:

Ganshorn Medizin Electronic GmbH

Address:

Industriestraße 6-8 97618 Niederlauer, Germany

declares, on it's own responsibility, that the following product:

Product designation:

Flow tube (disposable)

Product name:

ScoutTube®

Ref. No:

01942620

Is in conformity with the Medical Device Directive:

Medical Device Directive 93 / 42 / EEC

According to Annex I of this Directive the Accessory for SpiroScout is classified as:

Accssory:

Class Ila

ScoutTube® is in conformity with the harmonized standards the reference of which have been published in the "Official journal of the European Communities".

EN ISO 10993-1:2009

GANSHORN MEDIZIN ELECTRONIC GMBH

GANSHORN

GANSHORN Medizin Electronic GmbH Industriestrasse 6-8 · D-97618 Niederlauer Tel: +49 9771 6222 0 • Fax: +49 9771 6222 55

Chief Executive Officer

Jürgen Behringer

Niederlauer, November 01, 2018

Note: This document version is valid until November 2023 Declaration of EC-Conformity_ScoutTube_eng_rev02.doc