

Statement concerning the compatibility of Intersurgical breathing systems REF 2072000 and REF 2272000 with Draeger Oxylog® 2000 Plus, 3000 and 3000 Plus

This is to certify that Intersurgical breathing systems REF 2072000 and 2272000 are compatible and have been validated for use with the Draeger Oxylog® 2000 Plus, 3000 and the Draeger Oxylog® 3000 Plus.

Intersurgical manufactures a range of respiratory products, including breathing systems, which have been designed to perform and connect safely with devices and equipment made by other manufacturers. This document describes how compatibility is achieved.

Validation

Medical devices and medical device accessories have to be validated to ensure that they are safe and effective for their intended use. Manufacturers of devices which can be connected to other devices and accessories are obliged to determine the compatibility of their devices in order to be able to CE mark their products. Such compatibility can often be determined by the device complying with European or International device standards. If a relevant standard exists, and two or more devices comply with the standard, then the devices are likely to be compatible. Compatibility is also verified by testing during the design process.

Standards

The purpose of standards is to enable safe connections to be made between devices and equipment made by any manufacturer. Intersurgical breathing systems contain connectors, tubing, and devices, which comply with relevant International standards.

EC Competition Law: Treaty on the Functioning of the EU (TFEU)

The act of 'tying a product', which is the situation whereby a supplier makes the purchase of one product conditional upon the purchase of another distinct product from the same supplier, is prohibited by article 101 of the TFEU. Article 102 of the TFEU is contravened if a company with a dominant market position 'seeks to withdraw the warranty for a product should a customer refuse to buy accessories or consumables from the same supplier'.



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