

Quality System Approval CertificateMedical Devices Directive 93/42/EEC

The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (Medical Devices) Regulations (S.I. No. 252 of 1994)

APPROVES THE QUALITY SYSTEM APPLIED BY

ODC Industries

Rue Thomas Edison ZA Bois Vert Ploërmel 56800 France

to the Product Family

ErgoTouch FLY, ECO FLY, ErgoTouch GLIDE

GMDN Code: 47725

on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices Annex V.

The use of the NSAI Notified Body identification number 0050 in conjunction with CE Marking of

Conformance for this product family is hereby authorised.

Registration Number: 252.1164
Original Approval: 27 February 2018
Last Amended on: 16 December 2020
Remains valid until: 26 February 2023

Signed:

Approved by: Dr. Caroline Dore Geraghty Director, Medical Devices Approved by: Dr. Elaine Darcy

European Medical Device Operations Manager

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner. Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.