

EC Certificate Production Quality Assurance System FI17/07011-1

The management system of

Foshan Haiyue (HIROL) Medical Equipment Co.,Ltd

One of the Plants of Huang Chunxia's Properties
Second Stage, #5, Chaoyang Road
Nanhai National Eco-industrial Exemplary Park
Danzao Town, Nanhai District, Foshan, Guangdong Province
P.R. CHINA

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on Medical Devices, Annex V

For the following products

Dental units

Products covered are listed in Attachment 1 of this certificate

This certificate is valid from 19 October 2017 until 19 October 2022 and remains valid subject to satisfactory surveillance audits.

Recertification audit due before 19 October 2020

Issue 1. Certified since 19 October 2017

This certification is based on decision: FI17/07011P0

Authorised by

Tom Törn, Certification Director SGS Fimko Ltd., Notified Body 0598



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