EC Certificate Production Quality Assurance System: Certificate KR19/81826306

The management system of

Pearl Dent Co., Ltd.

(HO & Factory # 1) No.3-15B, Street No. 13,
Tan Binh Industrial Park, Ho Chi Minh City, N/A, Viet Nam

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 16 December 2019 until 07 November 2022
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 05 May 2006
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered WW/PCI/ 213470

This is a multi-site certification.
Additional site details are listed on subsequent pages.

Authorised by

Pieter Weterings
Certification Manager

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Pearl Dent Co., Ltd.

Directive 93/42/EEC

on medical devices, Annex V

Issue 1

Detailed scope

Gutta Percha Points

Sterile Absorbent Paper Points;

Sterile single-use dental injection needles.

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market

Additional facilities

(Factory # 2) Lo M6-M7, KCN Minh Hung-Han Quoc, X. Minh Hung H Chon Thanh, T. Binh Phuoc. Vietnam