



EC Certificate

Production Quality Assurance

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 058482 0010 Rev.00

Manufacturer:

Foshan Nanhai Hager Medical Machinery Co., Ltd.

F3, No.222 Lijia Industrial Area, Shang'ancun
Danzao Town, Nanhai District
528223 Foshan, Guangdong
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

**Shanghai International Holding
Corp. GmbH (Europe)**

Eiffestraße 80
20537 Hamburg
GERMANY

**Product
Category(ies):**

Integral Dental Unit

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.:

SH11441EXT01

Valid from:

2020-07-07

Valid until:

2025-07-08

Hans-Heiner Junker

Date, 2020-06-29



TÜV SÜD Product Service GmbH is Notified Body with Identification no. 0123



EC Certificate

Production Quality Assurance

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 058482 0010 Rev.00

Facility(ies):

F3, No.222 Lijia Industrial Area, Shang'ancun, Danzao Town
Nanhai District 528223 Foshan, Guangdong
PEOPLE'S REPUBLIC OF CHINA

RTIFIKAT ♦ CERTIFICATE ♦ 認証証書 ♦ СЕРТИФИКАТ ♦ CERTIFICADO ♦ CERT