

CERTIFICATE ◆ CERTIFICADO ◆ СЕРТИФИКАТ ◆ 認証証書 ◆ CERTIFICATE ◆ CERTIFICADO ◆ СЕРТИФИКАТ ◆ 認証証書 ◆ CERTIFICATE ◆ CERTIFICADO ◆ СЕРТИФИКАТ ◆ 認証証書 ◆

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II paragraph (4)
(Devices in Class IIa, IIb or III)

No. G1 15 04 53618 020

Manufacturer: ZHERMACK S.p.A
Via Bovazecchino, 100
45021 Badia Polesine (RO)
ITALY

Facility(ies): ZHERMACK S.p.A
Via Bovazecchino, 100, 45021 Badia Polesine (RO), ITALY

Product Category(ies): Disinfectants for medical devices;
Acrylic resins for dentures;
Dental restorative materials;
Steam Sterilizing unit

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: ITA258960

Valid from: 2018-05-06
Valid until: 2023-05-05



Hans-Heiner Junker

Date: 2018-05-06

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