

EC Certificate Full Quality Assurance System:
Certificate CN19/41140.00

The management system of

Shandong Huge Dental Material Corporation

Also trading as Rizhao HuGe Biomaterials Company, Ltd.

No. 68 Shanhai Road, Donggang District,
Rizhao City, Shandong Province, 276800, P.R. China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate

This certificate is valid from 18 May 2021 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 4. Certified since 05 June 2015.

Certification is based on reports numbered CNTAO 7323M

Multiple certificates have been issued for this scope.

The main certificate is numbered CN19/41140.00.

This is a multi-site certification.

Additional site details are listed on subsequent pages

Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639

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Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

Issue 4

Detailed scope

**Zirconia Block used in the area of Dentistry;
Glass Ionomer Cement used in the area of Dentistry;
Synthetic Polymer Teeth,
PMMA BLOCK used in the area of Dentistry;
Dual Cure Resin Cement used in the area of Dentistry;
Light Cure Dental Adhesive used in the area of Dentistry;
Light Cure Veneer Cement used in the area of Dentistry;
Universal Composite Restorative used in the area of Dentistry
Phosphoric Acid Etching Gel used in the area of Dentistry;
Ceramic Coupling Agent used in the area of Dentistry;
Enamel Coating Resin used in the area of Dentistry;
Flowable Composite Restorative used in the area of Dentistry;
Resin Modified Glass Ionomer Cement used in the area of Dentistry;
Invisible Orthodontic Appliance used in the area of Dentistry**

Additional facilities

**Rizhao HuGe Biomaterials Company, Ltd.
No.2 North Zhaoyang Road, District of Donggang,
Rizhao City, Shandong Province, 276800, P.R. China**