EC Certificate

Directive 93/42/EEC Annex V

Production Quality Assurance

Medical Devices

Registration No.: DD 60109667 0001

Report No.: 16805222 001

Manufacturer:

Henan Baistra Industries Corp.
Floor20, Buliding 16-C,
Henan National University Science Park(East Area)
NO.283 Xisanhuan Road
Zhengzhou 45000 Henan
China

Products:

Dental Burs
Dental Files
(see attachment for additional site included)

Expiry Date: 2027-05-22

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2022-06-24

Date: 2022-06-24

Notified Body

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.