Declaration of Conformity

Manufacturer:	Whose single Authorized Representative:
Henan Baistra Industries Corp. Address: Floor20, Buliding 16-C, Henan National University Science Park(East Area)NO.283 Xisanhuan Road Zhengzhou 45000 Henan China	Bader Europe Group SL Address: Rua da madanela, Nave 3 D,36350 Nigran-Pontevedra, Spain Tel: 0054-91165514549

We, the manufacturer, therewith declare under our sole responsibility that
The Medical Device
Product Name : Dental diamond burs, Dental carbide burs
Type / Model : TF,TR,CR,TC,EX, SF, SO, SR, WR, BR, BC,DI, SI ,BR-X ,FO, RA, FG etc

Of Class According to Annex V of Directive 93/42/EEC Class II a
Meet the provisions of Directive 93/42/EEC which apply to them
It bears the mark

CE 0197 TÜVRheinland

Applied Harmonized
EN 980:2008
EN 1041:2008
EN ISO 10993-1:2009/AC:2010
EN ISO 10993-5:2009
EN ISO 10993-10:2013
EN ISO 14971:2012
EN 62366:2008
EN 1641:2009
EN ISO 7405:2008/A1:2013
EN ISO 3823-2:2003/A1:2008

Conformity Assessment

Procedure MDD 93/42/EEC Annex V
Notified Body : Tüv Rheinland Porduct Safety Gmbh
Registration No: DD 60109667 001
Expirate date of the Certificate : 22 - 05 - 2026
Date CE mark was affixed :

Company : Henan Baistra Industries Corp.

Address: Floor20, Buliding 16-C, Henan National University Science Park(East Area),NO.283 Xisanhuan RoadZhengzhou 45000 Henan,China

Place, GuangDong

Name : WEI ZHAN JUN

Date : 2021 / 06 / 24

Legally signature,

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

TÜVRheinland®

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 Diamond Burs
Dental Carbide Burs
(see attachment for additional site included)

Expiry Date: 2026-05-22

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: 2021-06-24

Date: 2021-06-24

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

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.

Digitally signed by Romanenco Alexandru
Date: 2024.01.15 11:08:34 EET
Reason: MoldSign Signature
Location: Moldova