

Declaration of Conformity

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



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,

