

Hangzhou Xingchen 3B Dental Instrument & Material Co., Ltd.

Add: No 619, Guoting Street, Chunjiang Subdistrict, Fuyang District, 311421, Hangzhou, P R China
Website: www.ortho3b.com Telephone: 0086 571 8765 5303

Manufacturer's Declaration

In relation to Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 regards the transitional provisions for medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*¹
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Hangzhou Xingchen 3B Dental Instrument & Material Co., Ltd.
Manufacturer address and contact details	No 619, Guoting Street, Chunjiang Subdistrict, Fuyang District, 311421, Hangzhou, P R China Contact: Mr. Yongfei Zhou Phone: +86 138 5713 5459 E-mail: 3bortho.n1@ortho3b.com
Single Registration Number (SRN)	CN-MF-000029873

Authorised Representative name	Shanghai International Holding Corp.GmbH (Europe)
Authorised Representative address and contact details	Eiffestrasse 80, Hamburg, 20537, Germany Contact person: Jin Liang Contact phone number: 0049 40 2513 175 E-mail: shholding@hotmail.com
Single Registration Number (SRN)	DE-AR-000000001

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Notified body name	TUV SUD Product Service GmbH
Notified body number	0123
Directive Certificate number(s) to which this confirmation is made	G2 074269 0005 Rev. 02 / CL 074269 0010 Rev. 00
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	2024-05-26
End date of extended validity/transition period	2028-12-31

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*²
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➤ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

Choose applicable statements:

- Expired *before* 20 March 2023:
 - Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
 - A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

杭州兴晨三比
医疗器械有限公司
(盖章)

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- A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.
- Expired/expires *after* 20 March 2023:

Choose one applicable statement:

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.



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➤ Upclassified devices

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intend to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ Quality Management System (QMS)

Choose one applicable statement:

- A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- A QMS in accordance with Article 10(9) MDR is in place.
- A notified body has issued the attached certificate for the MDR-compliant QMS.

➤ Device(s) as listed in the attached schedule

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: Hangzhou Xingchen 3B Dental Instrument & Material Co., Ltd.

Location & Date: Hangzhou, P R China, 2024-06-04

Signature, Print Name, Title:

Guozhong Li

Regulatory Person: Mr. Guozhong Li,

Contact Details: +86 180 06789756



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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) ³ (e.g., device name, family/group name device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
Orthodontic brackets	G2 074269 0005 Rev. 02	2024-05-26	TUV SUD Product Service GmbH 0123	TUV SUD Product Service GmbH 0123	2028-12-31	
Orthodontic tubes	G2 074269 0005 Rev. 02	2024-05-26	TUV SUD Product Service GmbH 0123	TUV SUD Product Service GmbH 0123	2028-12-31	
Orthodontic bands	G2 074269 0005 Rev. 02	2024-05-26	TUV SUD Product Service GmbH 0123	TUV SUD Product Service GmbH 0123	2028-12-31	
Lingual buttons	G2 074269 0005 Rev. 02	2024-05-26	TUV SUD Product Service GmbH 0123	TUV SUD Product Service GmbH 0123	2028-12-31	
Sliding hooks	G2 074269 0005 Rev. 02	2024-05-26	TUV SUD Product Service GmbH 0123	TUV SUD Product Service GmbH 0123	2028-12-31	