

EU DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Zhejiang Baitai Medical Technology CO., LTD.
No.1 Longjing Road, Jinchuan Street,
Zhejiang, 324299 China**

Name and address of the European
Authorized Representative: **MHC Technology
717 chemin Sainte Colombe
06140 VENCE (France)**

We declare under our sole responsibility
that the medical device: **Steam Sterilizer (Autoclave)**

Product code:
Basic UDI-DI **BTD45 / BTD29 / BTD23-A / BTD23-B / BTD17-A / BTD17-B
BTD12 / BTD8**

Intended purpose: **Using high-temperature, high-pressure steam to
penetrate and kill microorganisms in instruments,
protheses and implants in medical and dental
practices, hospitals and CSSDs,
dental laboratoires, tatto and piercing studio,
and foot care salons.**

of class: **IIA**

according to Annex VIII of Regulation (EU) 2017/745

meets the provisions of the Regulation (EU) 2017/745 which apply to it. This declaration is supported by the
Quality System approval to ISO13485.

All supporting documentation is retained at the premises of the manufacturer.

Conformity assessment procedure: **EU Declaration of Conformity referred to in
MDR article 19**

Certificate: **NA**

Notified Body: **NA**

**Changshan, Quzhou,
January 1, 2024**

**Ren Lianggang
General Manager**

Place, date

Name, title