



## EC DECLARATION OF CONFORMITY

The following EC declaration of conformity exemplifies the required content according to Directive 93/42/EEC.



**EC DECLARATION OF CONFORMITY**

Name and address of the manufacturer:

BAIN MEDICAL EQUIPMENT (GUANGZHOU) CO.,LTD

No.10, Juncheng Road, Eastern Area, Economic and Technological Development District, Guangzhou 510760, China.

We declare under our sole responsibility that

the medical device: **Tubing Sets for Hemodialysis**

UMDNS Code: 11225

GMDN Code: 34999

Brand Name: DORA

Model codes:

Model	Model	Model	Model	Model
BAIN-BL-001E	BAIN-BL-025E	BAIN-BL-049E	BAIN-BL-073E	BAIN-BL-097E
<i>BAIN-BL-002E</i>	BAIN-BL-026E	BAIN-BL-050E	BAIN-BL-074E	BAIN-BL-098E
BAIN-BL-003E	BAIN-BL-027E	BAIN-BL-051E	BAIN-BL-075E	BAIN-BL-099E
BAIN-BL-004E	BAIN-BL-028E	BAIN-BL-052E	BAIN-BL-076E	BAIN-BL-100E
BAIN-BL-005E	BAIN-BL-029E	BAIN-BL-053E	BAIN-BL-077E	BAIN-BL-101E
BAIN-BL-006E	BAIN-BL-030E	BAIN-BL-054E	BAIN-BL-078E	BAIN-BL-102E
BAIN-BL-007E	BAIN-BL-031E	BAIN-BL-055E	BAIN-BL-079E	BAIN-BL-103E
BAIN-BL-008E	BAIN-BL-032E	BAIN-BL-056E	BAIN-BL-080E	BAIN-BL-104E
BAIN-BL-009E	BAIN-BL-033E	BAIN-BL-057E	BAIN-BL-081E	BAIN-BL-105E
BAIN-BL-010E	BAIN-BL-034E	BAIN-BL-058E	BAIN-BL-082E	BAIN-BL-106E
BAIN-BL-011E	BAIN-BL-035E	BAIN-BL-059E	BAIN-BL-083E	BAIN-BL-107E
BAIN-BL-012E	BAIN-BL-036E	BAIN-BL-060E	BAIN-BL-084E	BAIN-BL-108E
BAIN-BL-013E	BAIN-BL-037E	BAIN-BL-061E	BAIN-BL-085E	BAIN-BL-109E
BAIN-BL-014E	BAIN-BL-038E	BAIN-BL-062E	BAIN-BL-086E	BAIN-BL-110E
BAIN-BL-015E	BAIN-BL-039E	BAIN-BL-063E	BAIN-BL-087E	BAIN-BL-111E
BAIN-BL-016E	BAIN-BL-040E	BAIN-BL-064E	BAIN-BL-088E	BAIN-BL-112E
BAIN-BL-017E	BAIN-BL-041E	BAIN-BL-065E	BAIN-BL-089E	BAIN-BL-113E
BAIN-BL-018E	BAIN-BL-042E	BAIN-BL-066E	BAIN-BL-090E	BAIN-BL-114E
BAIN-BL-019E	BAIN-BL-043E	BAIN-BL-067E	BAIN-BL-091E	BAIN-BL-115E
BAIN-BL-020E	BAIN-BL-044E	BAIN-BL-068E	BAIN-BL-092E	BAIN-BL-116E
BAIN-BL-021E	BAIN-BL-045E	BAIN-BL-069E	BAIN-BL-093E	BAIN-BL-117E
BAIN-BL-022E	BAIN-BL-046E	BAIN-BL-070E	BAIN-BL-094E	BAIN-BL-118E
BAIN-BL-023E	BAIN-BL-047E	BAIN-BL-071E	BAIN-BL-095E	-----
BAIN-BL-024E	BAIN-BL-048E	BAIN-BL-072E	BAIN-BL-096E	-----



## EC DECLARATION OF CONFORMITY

of class: IIa

according to Rule 2 of annex IX of directive 93/42/EEC

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure: **Directive 93/42/EEC Annex II, excluding Section 4**

Registration No.: **HD1518511-1**

Notified Body: **TÜV Rheinland LGA Products GmbH  
Tillystraße 2  
90431 Nürnberg  
Deutschland  
CE 0197**

Guangzhou, 20/05/2021

Place, date /

MU Fangzhen, Management Representative

Name and function