



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.

Manufacturing site:

Floor 1-3 Building A, No. 296, Ruixiang Road, Huangpu District, Guangzhou, 510760, Guangdong, P.R. China

We declare under our sole responsibility that

the medical device: **Disposable A.V.Fistula Needle Sets**

UMDNS Code: 12741

GMDN Code: 12741

Brand Name: DORA

Model codes:

Single packing models			Double packing models
BAIN-A.V.F-001G	BAIN-A.V.F-001AG	BAIN-A.V.F-001VG	BAIN-A.V.F-001TG
BAIN-A.V.F-002G	BAIN-A.V.F-002AG	BAIN-A.V.F-002VG	BAIN-A.V.F-002TG
BAIN-A.V.F-003G	BAIN-A.V.F-003AG	BAIN-A.V.F-003VG	BAIN-A.V.F-003TG
BAIN-A.V.F-004G	BAIN-A.V.F-004AG	BAIN-A.V.F-004VG	BAIN-A.V.F-004TG
BAIN-A.V.F-005G	BAIN-A.V.F-005AG	BAIN-A.V.F-005VG	BAIN-A.V.F-005TG
BAIN-A.V.F-006G	BAIN-A.V.F-006AG	BAIN-A.V.F-006VG	BAIN-A.V.F-006TG
BAIN-A.V.F-007G	BAIN-A.V.F-007AG	BAIN-A.V.F-007VG	BAIN-A.V.F-007TG
BAIN-A.V.F-008G	BAIN-A.V.F-008AG	BAIN-A.V.F-008VG	BAIN-A.V.F-008TG
BAIN-A.V.F-009G	BAIN-A.V.F-009AG	BAIN-A.V.F-009VG	BAIN-A.V.F-009TG
BAIN-A.V.F-010G	BAIN-A.V.F-010AG	BAIN-A.V.F-010VG	BAIN-A.V.F-010TG
BAIN-A.V.F-011G	BAIN-A.V.F-011AG	BAIN-A.V.F-011VG	BAIN-A.V.F-011TG
BAIN-A.V.F-012G	BAIN-A.V.F-012AG	BAIN-A.V.F-012VG	BAIN-A.V.F-012TG
BAIN-A.V.F-013G	BAIN-A.V.F-013AG	BAIN-A.V.F-013VG	BAIN-A.V.F-013TG
BAIN-A.V.F-014G	BAIN-A.V.F-014AG	BAIN-A.V.F-014VG	BAIN-A.V.F-014TG
BAIN-A.V.F-015G	BAIN-A.V.F-015AG	BAIN-A.V.F-015VG	BAIN-A.V.F-015TG
BAIN-A.V.F-016G	BAIN-A.V.F-016AG	BAIN-A.V.F-016VG	BAIN-A.V.F-016TG
BAIN-A.V.F-017G	BAIN-A.V.F-017AG	BAIN-A.V.F-017VG	BAIN-A.V.F-017TG
BAIN-A.V.F-018G	BAIN-A.V.F-018AG	BAIN-A.V.F-018VG	BAIN-A.V.F-018TG
BAIN-A.V.F-019G	BAIN-A.V.F-019AG	BAIN-A.V.F-019VG	BAIN-A.V.F-019TG
BAIN-A.V.F-020G	BAIN-A.V.F-020AG	BAIN-A.V.F-020VG	BAIN-A.V.F-020TG
BAIN-A.V.F-021G	BAIN-A.V.F-021AG	BAIN-A.V.F-021VG	BAIN-A.V.F-021TG
BAIN-A.V.F-022G	BAIN-A.V.F-022AG	BAIN-A.V.F-022VG	BAIN-A.V.F-022TG
BAIN-A.V.F-023G	BAIN-A.V.F-023AG	BAIN-A.V.F-023VG	BAIN-A.V.F-023TG
BAIN-A.V.F-024G	BAIN-A.V.F-024AG	BAIN-A.V.F-024VG	BAIN-A.V.F-024TG
BAIN-A.V.F-025G	BAIN-A.V.F-025AG	BAIN-A.V.F-025VG	BAIN-A.V.F-025TG
BAIN-A.V.F-026G	BAIN-A.V.F-026AG	BAIN-A.V.F-026VG	BAIN-A.V.F-026TG

Doc: BM3-TF-AVF-04 (G) rev.: F.8 20/05/2021

Add.: No.10,Juncheng Road,Eastern Area,GETDD,China.510760

Tel:86-20-82265249 Fax:86-20-32067500

Website:www.bainmedical.com



BAIN-A.V.F-027G	BAIN-A.V.F-027AG	BAIN-A.V.F-027VG	BAIN-A.V.F-027TG
BAIN-A.V.F-028G	BAIN-A.V.F-028AG	BAIN-A.V.F-028VG	BAIN-A.V.F-028TG
BAIN-A.V.F-029G	BAIN-A.V.F-029AG	BAIN-A.V.F-029VG	BAIN-A.V.F-029TG
BAIN-A.V.F-030G	BAIN-A.V.F-030AG	BAIN-A.V.F-030VG	BAIN-A.V.F-030TG
BAIN-A.V.F-031G	BAIN-A.V.F-031AG	BAIN-A.V.F-031VG	BAIN-A.V.F-031TG
BAIN-A.V.F-032G	BAIN-A.V.F-032AG	BAIN-A.V.F-032VG	BAIN-A.V.F-032TG
BAIN-A.V.F-033G	BAIN-A.V.F-033AG	BAIN-A.V.F-033VG	BAIN-A.V.F-033TG
BAIN-A.V.F-034G	BAIN-A.V.F-034AG	BAIN-A.V.F-034VG	BAIN-A.V.F-034TG
BAIN-A.V.F-035G	BAIN-A.V.F-035AG	BAIN-A.V.F-035VG	BAIN-A.V.F-035TG
BAIN-A.V.F-036G	BAIN-A.V.F-036AG	BAIN-A.V.F-036VG	BAIN-A.V.F-036TG
BAIN-A.V.F-037G	BAIN-A.V.F-037AG	BAIN-A.V.F-037VG	BAIN-A.V.F-037TG
BAIN-A.V.F-038G	BAIN-A.V.F-038AG	BAIN-A.V.F-038VG	BAIN-A.V.F-038TG
BAIN-A.V.F-039G	BAIN-A.V.F-039AG	BAIN-A.V.F-039VG	BAIN-A.V.F-039TG
BAIN-A.V.F-040G	BAIN-A.V.F-040AG	BAIN-A.V.F-040VG	BAIN-A.V.F-040TG
BAIN-A.V.F-041G	BAIN-A.V.F-041AG	BAIN-A.V.F-041VG	BAIN-A.V.F-041TG
BAIN-A.V.F-042G	BAIN-A.V.F-042AG	BAIN-A.V.F-042VG	BAIN-A.V.F-042TG
BAIN-A.V.F-043G	BAIN-A.V.F-043AG	BAIN-A.V.F-043VG	BAIN-A.V.F-043TG
BAIN-A.V.F-044G	BAIN-A.V.F-044AG	BAIN-A.V.F-044VG	BAIN-A.V.F-044TG
BAIN-A.V.F-045G	BAIN-A.V.F-045AG	BAIN-A.V.F-045VG	BAIN-A.V.F-045TG
BAIN-A.V.F-046G	BAIN-A.V.F-046AG	BAIN-A.V.F-046VG	BAIN-A.V.F-046TG
BAIN-A.V.F-047G	BAIN-A.V.F-047AG	BAIN-A.V.F-047VG	BAIN-A.V.F-047TG
BAIN-A.V.F-048G	BAIN-A.V.F-048AG	BAIN-A.V.F-048VG	BAIN-A.V.F-048TG
BAIN-A.V.F-049G	BAIN-A.V.F-049AG	BAIN-A.V.F-049VG	BAIN-A.V.F-049TG
BAIN-A.V.F-050G	BAIN-A.V.F-050AG	BAIN-A.V.F-050VG	BAIN-A.V.F-050TG
BAIN-A.V.F-051G	BAIN-A.V.F-051AG	BAIN-A.V.F-051VG	BAIN-A.V.F-051TG
BAIN-A.V.F-052G	BAIN-A.V.F-052AG	BAIN-A.V.F-052VG	BAIN-A.V.F-052TG
BAIN-A.V.F-053G	BAIN-A.V.F-053AG	BAIN-A.V.F-053VG	BAIN-A.V.F-053TG
BAIN-A.V.F-054G	BAIN-A.V.F-054AG	BAIN-A.V.F-054VG	BAIN-A.V.F-054TG
BAIN-A.V.F-055G	BAIN-A.V.F-055AG	BAIN-A.V.F-055VG	BAIN-A.V.F-055TG
BAIN-A.V.F-056G	BAIN-A.V.F-056AG	BAIN-A.V.F-056VG	BAIN-A.V.F-056TG
BAIN-A.V.F-057G	BAIN-A.V.F-057AG	BAIN-A.V.F-057VG	BAIN-A.V.F-057TG
BAIN-A.V.F-058G	BAIN-A.V.F-058AG	BAIN-A.V.F-058VG	BAIN-A.V.F-058TG
BAIN-A.V.F-059G	BAIN-A.V.F-059AG	BAIN-A.V.F-059VG	BAIN-A.V.F-059TG
BAIN-A.V.F-060G	BAIN-A.V.F-060AG	BAIN-A.V.F-060VG	BAIN-A.V.F-060TG
BAIN-A.V.F-061G	BAIN-A.V.F-061AG	BAIN-A.V.F-061VG	BAIN-A.V.F-061TG
BAIN-A.V.F-062G	BAIN-A.V.F-062AG	BAIN-A.V.F-062VG	BAIN-A.V.F-062TG
BAIN-A.V.F-063G	BAIN-A.V.F-063AG	BAIN-A.V.F-063VG	BAIN-A.V.F-063TG
BAIN-A.V.F-064G	BAIN-A.V.F-064AG	BAIN-A.V.F-064VG	BAIN-A.V.F-064TG
BAIN-A.V.F-065G	BAIN-A.V.F-065AG	BAIN-A.V.F-065VG	BAIN-A.V.F-065TG
BAIN-A.V.F-066G	BAIN-A.V.F-066AG	BAIN-A.V.F-066VG	BAIN-A.V.F-066TG
BAIN-A.V.F-067G	BAIN-A.V.F-067AG	BAIN-A.V.F-067VG	BAIN-A.V.F-067TG
BAIN-A.V.F-068G	BAIN-A.V.F-068AG	BAIN-A.V.F-068VG	BAIN-A.V.F-068TG

Doc: BM3-TF-AVF-04 (G) rev.: F.8 20/05/2021



BAIN-A.V.F-069G	BAIN-A.V.F-069AG	BAIN-A.V.F-069VG	BAIN-A.V.F-069TG
BAIN-A.V.F-070G	BAIN-A.V.F-070AG	BAIN-A.V.F-070VG	BAIN-A.V.F-070TG
BAIN-A.V.F-071G	BAIN-A.V.F-071AG	BAIN-A.V.F-071VG	BAIN-A.V.F-071TG
BAIN-A.V.F-072G	BAIN-A.V.F-072AG	BAIN-A.V.F-072VG	BAIN-A.V.F-072TG
BAIN-A.V.F-073G	BAIN-A.V.F-073AG	BAIN-A.V.F-073VG	BAIN-A.V.F-073TG
BAIN-A.V.F-074G	BAIN-A.V.F-074AG	BAIN-A.V.F-074VG	BAIN-A.V.F-074TG
BAIN-A.V.F-075G	BAIN-A.V.F-075AG	BAIN-A.V.F-075VG	BAIN-A.V.F-075TG
BAIN-A.V.F-076G	BAIN-A.V.F-076AG	BAIN-A.V.F-076VG	BAIN-A.V.F-076TG
BAIN-A.V.F-077G	BAIN-A.V.F-077AG	BAIN-A.V.F-077VG	BAIN-A.V.F-077TG
BAIN-A.V.F-078G	BAIN-A.V.F-078AG	BAIN-A.V.F-078VG	BAIN-A.V.F-078TG
BAIN-A.V.F-079G	BAIN-A.V.F-079AG	BAIN-A.V.F-079VG	BAIN-A.V.F-079TG
BAIN-A.V.F-080G	BAIN-A.V.F-080AG	BAIN-A.V.F-080VG	BAIN-A.V.F-080TG
BAIN-A.V.F-081G	BAIN-A.V.F-081AG	BAIN-A.V.F-081VG	BAIN-A.V.F-081TG
BAIN-A.V.F-082G	BAIN-A.V.F-082AG	BAIN-A.V.F-082VG	BAIN-A.V.F-082TG
BAIN-A.V.F-083G	BAIN-A.V.F-083AG	BAIN-A.V.F-083VG	BAIN-A.V.F-083TG
BAIN-A.V.F-084G	BAIN-A.V.F-084AG	BAIN-A.V.F-084VG	BAIN-A.V.F-084TG
BAIN-A.V.F-085G	BAIN-A.V.F-085AG	BAIN-A.V.F-085VG	BAIN-A.V.F-085TG
BAIN-A.V.F-086G	BAIN-A.V.F-086AG	BAIN-A.V.F-086VG	BAIN-A.V.F-086TG
BAIN-A.V.F-087G	BAIN-A.V.F-087AG	BAIN-A.V.F-087VG	BAIN-A.V.F-087TG
BAIN-A.V.F-088G	BAIN-A.V.F-088AG	BAIN-A.V.F-088VG	BAIN-A.V.F-088TG
BAIN-A.V.F-089G	BAIN-A.V.F-089AG	BAIN-A.V.F-089VG	BAIN-A.V.F-089TG
BAIN-A.V.F-090G	BAIN-A.V.F-090AG	BAIN-A.V.F-090VG	BAIN-A.V.F-090TG
BAIN-A.V.F-091G	BAIN-A.V.F-091AG	BAIN-A.V.F-091VG	BAIN-A.V.F-091TG
BAIN-A.V.F-092G	BAIN-A.V.F-092AG	BAIN-A.V.F-092VG	BAIN-A.V.F-092TG
BAIN-A.V.F-093G	BAIN-A.V.F-093AG	BAIN-A.V.F-093VG	BAIN-A.V.F-093TG
BAIN-A.V.F-094G	BAIN-A.V.F-094AG	BAIN-A.V.F-094VG	BAIN-A.V.F-094TG
BAIN-A.V.F-095G	BAIN-A.V.F-095AG	BAIN-A.V.F-095VG	BAIN-A.V.F-095TG
BAIN-A.V.F-096G	BAIN-A.V.F-096AG	BAIN-A.V.F-096VG	BAIN-A.V.F-096TG
BAIN-A.V.F-097G	BAIN-A.V.F-097AG	BAIN-A.V.F-097VG	BAIN-A.V.F-097TG
BAIN-A.V.F-098G	BAIN-A.V.F-098AG	BAIN-A.V.F-098VG	BAIN-A.V.F-098TG
BAIN-A.V.F-099G	BAIN-A.V.F-099AG	BAIN-A.V.F-099VG	BAIN-A.V.F-099TG
BAIN-A.V.F-100G	BAIN-A.V.F-100AG	BAIN-A.V.F-100VG	BAIN-A.V.F-100TG

of class: IIa

according to Rule7 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

Doc: BM3-TF-AVF-04 (G) rev.: F.8 20/05/2021



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