



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	Model
BAIN-BL-001	BAIN-BL-050	BAIN-BL-099	BAIN-BL-148	BAIN-BL-197	BAIN-BL-246
BAIN-BL-002	BAIN-BL-051	BAIN-BL-100	BAIN-BL-149	BAIN-BL-198	BAIN-BL-247
BAIN-BL-003	BAIN-BL-052	BAIN-BL-101	BAIN-BL-150	BAIN-BL-199	BAIN-BL-248
BAIN-BL-004	BAIN-BL-053	BAIN-BL-102	BAIN-BL-151	BAIN-BL-200	BAIN-BL-249
BAIN-BL-005	BAIN-BL-054	BAIN-BL-103	BAIN-BL-152	BAIN-BL-201	BAIN-BL-250
BAIN-BL-006	BAIN-BL-055	BAIN-BL-104	BAIN-BL-153	BAIN-BL-202	BAIN-BL-251
BAIN-BL-007	BAIN-BL-056	BAIN-BL-105	BAIN-BL-154	BAIN-BL-203	BAIN-BL-252
BAIN-BL-008	BAIN-BL-057	BAIN-BL-106	BAIN-BL-155	BAIN-BL-204	BAIN-BL-253
BAIN-BL-009	BAIN-BL-058	BAIN-BL-107	BAIN-BL-156	BAIN-BL-205	BAIN-BL-254
BAIN-BL-010	BAIN-BL-059	BAIN-BL-108	BAIN-BL-157	BAIN-BL-206	BAIN-BL-255
BAIN-BL-011	BAIN-BL-060	BAIN-BL-109	BAIN-BL-158	BAIN-BL-207	BAIN-BL-256
BAIN-BL-012	BAIN-BL-061	BAIN-BL-110	BAIN-BL-159	BAIN-BL-208	BAIN-BL-257
BAIN-BL-013	BAIN-BL-062	BAIN-BL-111	BAIN-BL-160	BAIN-BL-209	BAIN-BL-258
BAIN-BL-014	BAIN-BL-063	BAIN-BL-112	BAIN-BL-161	BAIN-BL-210	BAIN-BL-259
BAIN-BL-015	BAIN-BL-064	BAIN-BL-113	BAIN-BL-162	BAIN-BL-211	BAIN-BL-260
BAIN-BL-016	BAIN-BL-065	BAIN-BL-114	BAIN-BL-163	BAIN-BL-212	BAIN-BL-261
BAIN-BL-017	BAIN-BL-066	BAIN-BL-115	BAIN-BL-164	BAIN-BL-213	BAIN-BL-262
BAIN-BL-018	BAIN-BL-067	BAIN-BL-116	BAIN-BL-165	BAIN-BL-214	BAIN-BL-263
BAIN-BL-019	BAIN-BL-068	BAIN-BL-117	BAIN-BL-166	BAIN-BL-215	BAIN-BL-264
BAIN-BL-020	BAIN-BL-069	BAIN-BL-118	BAIN-BL-167	BAIN-BL-216	BAIN-BL-265
BAIN-BL-021	BAIN-BL-070	BAIN-BL-119	BAIN-BL-168	BAIN-BL-217	BAIN-BL-266
BAIN-BL-022	BAIN-BL-071	BAIN-BL-120	BAIN-BL-169	BAIN-BL-218	BAIN-BL-267
BAIN-BL-023	BAIN-BL-072	BAIN-BL-121	BAIN-BL-170	BAIN-BL-219	BAIN-BL-268
BAIN-BL-024	BAIN-BL-073	BAIN-BL-122	BAIN-BL-171	BAIN-BL-220	BAIN-BL-269
BAIN-BL-025	BAIN-BL-074	BAIN-BL-123	BAIN-BL-172	BAIN-BL-221	BAIN-BL-270
BAIN-BL-026	BAIN-BL-075	BAIN-BL-124	BAIN-BL-173	BAIN-BL-222	BAIN-BL-271
BAIN-BL-027	BAIN-BL-076	BAIN-BL-125	BAIN-BL-174	BAIN-BL-223	BAIN-BL-272
BAIN-BL-028	BAIN-BL-077	BAIN-BL-126	BAIN-BL-175	BAIN-BL-224	BAIN-BL-273
BAIN-BL-029	BAIN-BL-078	BAIN-BL-127	BAIN-BL-176	BAIN-BL-225	BAIN-BL-274
BAIN-BL-030	BAIN-BL-079	BAIN-BL-128	BAIN-BL-177	BAIN-BL-226	BAIN-BL-275

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BAIN-BL-031	BAIN-BL-080	BAIN-BL-129	BAIN-BL-178	BAIN-BL-227	BAIN-BL-276
BAIN-BL-032	BAIN-BL-081	BAIN-BL-130	BAIN-BL-179	BAIN-BL-228	BAIN-BL-277
BAIN-BL-033	BAIN-BL-082	BAIN-BL-131	BAIN-BL-180	BAIN-BL-229	BAIN-BL-278
BAIN-BL-034	BAIN-BL-083	BAIN-BL-132	BAIN-BL-181	BAIN-BL-230	BAIN-BL-279
BAIN-BL-035	BAIN-BL-084	BAIN-BL-133	BAIN-BL-182	BAIN-BL-231	BAIN-BL-280
BAIN-BL-036	BAIN-BL-085	BAIN-BL-134	BAIN-BL-183	BAIN-BL-232	BAIN-BL-281
BAIN-BL-037	BAIN-BL-086	BAIN-BL-135	BAIN-BL-184	BAIN-BL-233	BAIN-BL-282
BAIN-BL-038	BAIN-BL-087	BAIN-BL-136	BAIN-BL-185	BAIN-BL-234	BAIN-BL-283
BAIN-BL-039	BAIN-BL-088	BAIN-BL-137	BAIN-BL-186	BAIN-BL-235	BAIN-BL-284
BAIN-BL-040	BAIN-BL-089	BAIN-BL-138	BAIN-BL-187	BAIN-BL-236	BAIN-BL-285
BAIN-BL-041	BAIN-BL-090	BAIN-BL-139	BAIN-BL-188	BAIN-BL-237	BAIN-BL-286
BAIN-BL-042	BAIN-BL-091	BAIN-BL-140	BAIN-BL-189	BAIN-BL-238	BAIN-BL-287
BAIN-BL-043	BAIN-BL-092	BAIN-BL-141	BAIN-BL-190	BAIN-BL-239	BAIN-BL-288
BAIN-BL-044	BAIN-BL-093	BAIN-BL-142	BAIN-BL-191	BAIN-BL-240	BAIN-BL-289
BAIN-BL-045	BAIN-BL-094	BAIN-BL-143	BAIN-BL-192	BAIN-BL-241	BAIN-BL-290
BAIN-BL-046	BAIN-BL-095	BAIN-BL-144	BAIN-BL-193	BAIN-BL-242	BAIN-BL-291
BAIN-BL-047	BAIN-BL-096	BAIN-BL-145	BAIN-BL-194	BAIN-BL-243	BAIN-BL-292
BAIN-BL-048	BAIN-BL-097	BAIN-BL-146	BAIN-BL-195	BAIN-BL-244	BAIN-BL-293
BAIN-BL-049	BAIN-BL-098	BAIN-BL-147	BAIN-BL-196	BAIN-BL-245	BAIN-BL-294
BAIN-BL-295	BAIN-BL-296	BAIN-BL-297	----	----	---

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

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