

Legal manufacturer: Huaian Tianda Medical Instruments Co., Ltd.
Street: No.106, East Songjiang Road, Huaiyin Economic & Technological Development Zone,
ZIP code, city: Huaian, 223002 Jiangsu,
Country: P.R. China
Order no.: 244367738
Technical documentation (TD) title or identifier: TD/CE-001
TD issue date/version: Rev A/10, 2021-10-14
Generic device group: N/A
Device subcategory: MD 0106 Non-active instruments
Product name: Disposable surgical blades (with and without handle)
Type(s)/model(s): Type: #9,10,11,12, 15, 17, 20,21,22,23,24,24d,34
#10 With handle was as sample during audit

Review substantiation: **This review is based on a sampling plan** for technical documentation reviews
 Essential element for the evaluation of model(s)/variant(s) in existing product group

Auditor /expert's recommendation:

- Within the scope of the review, the reviewer obtained evidence that the technical documentation fulfills relevant requirements of the medical device Directive 93/42/EEC.
- All applicable quality related processes have been evaluated during previous audits (see e.g. audit report no. [XX](#)).
- An additional audit was performed to assess relevant processes to introduce model(s)/variant(s) in existing product group. See audit report with no. [XX](#), provided together with this review report.
- Within the scope of the review, the reviewer obtained evidence that the submitted technical documentation **does not** completely fulfill relevant requirements of the Medical Device Directive 93/42/EEC.

It is recommended that the TÜV Rheinland LGA Products GmbH notified body (0197) certificate **DD60147743 0001** should

be updated for the scope: [Enter text here](#) via Letter: update of information to certificate (MS-0045446)

with reference to (Significant) Change Notification: (SCN dated [2021-09-10](#))

remain valid with unchanged scope

be restricted for the above mentioned product: [Enter text here](#) via Letter: update of information to certificate (MS-0045446)

Review time: on-site: [XX](#) hours off-site: 16 hours

Revision history

Report Number	Date of Report / Name of reviewer	Description of Change
244367738-300 Rev 0	2022-02-25 / Ms. Grace Ji	Initial report

25/02/2022

X *Grace Ji*

reviewer 1
Signed by: Grace Ji

X

reviewer 2