Summary of the Clinical Evaluation (Version 02, October 2017)

Dated 2017-11-08

Medical Device	Mighty Medic
Manufacturer	Storz & Bickel GmbH & Co. KG In Grubenäcker 5-9 D-78532 Tuttlingen
Basis of Evaluation	Council Directive 93/42/EEC (MDD)
Task	Evaluation of performance, safety, and the benefit-risk ratio with regard to the requirements of the Directive

Documents taken into consideration

- Mighty_Medic_Gebrauchsanweisung (MMAL-30-209-DE 06-2017)
- MIghty Medic Risiko Management
- Current Post Market Surveillance (PMS) data
- CB_MightyMedic_Usability
- CB_MightyMedic_en
- CB_MightyMedic_Konstruktive_Sicherheit
- CB_MightyMedic_Medical_Electrical_Equipment
- CB_MightyMedic_TestReport
- Evaluation of Clinical Data – Franjo Grotenhermen
- Produktbeschreibung_Volcano_Mighty_Medic
- Mighty Medic Verdampfer – Ablaufplan zu Biokompatibilität und mikrobiologischer Reinheit des Lippenteils mit Mundstück
- Scientific literature

Result	From a clinical point of view, the Mighty Medic meets the Essential Requirements MDD ER1, MDD ER3, and MDD ER6 as stipulated in Annex I, Directive 93/42/EEC at the time of compilation of the clinical evaluation.

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