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

Dated 2017-11-08

Medical Device	Volcano Medic Vaporization System
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

- Volcano_Medic_Verdampfer_Gebrauchsanweisung (VMAL-50-212-DE 02-2017)
- Volcano Medic Risiko Management
- Current Post Market Surveillance (PMS) data
- CB_VolcanoMedic_Usability
- CB_VolcanoMedic_Konstruktive_Sicherheit
- CB_VolcanoMedic_Medical_ElectricalEquipment
- CB_VolcanoMedic_TestReport
- VolcanoMedic Usability Engineering File
- Evaluation of Clinical Data – Franjo Grotenhermen
- Produktbeschreibung_Volcano_Mighty_Medic
- Volcano Medic Verdampfungssystem – Biologische Sicherheit und Hygiene
- Scientific literature

Result

From a clinical point of view, the Volcano Medic Vaporization System 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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