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 Tuttingen

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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