

EC Declaration of Conformity Template Machinery Directive 2006/42/EC

declaration - Document No. SAMPLE-DOC-CE-001 - Rev B SAMPLE

Technical Document - GentlemanPharmed Pharmaceutical Engineering Division
Category: Company

Template declaration issued per machine serial number for CE-marked supply, listing directives and harmonised standards.

SPECIFICATIONS & VALIDATION OVERVIEW:

- Contact Material: Stainless Steel AISI 316L (Mirror polished Ra <= 0.4 um)
- Non-contact Structure: Stainless Steel AISI 304 (Scotch-Brite Satin Finish)
- Automation & HMI: Siemens S7-1500 / Allen-Bradley ControlLogix PLC with 21 CFR Part 11 / Audit Trail
- Documentation Package: Full DQ, IQ, OQ, PQ Protocols, 3.1 Mill Certificates, Calibration Records
- Compliance Standards: WHO-GMP, USFDA 21 CFR Part 211, EU-GMP Annex 1, ISO 9001:2015, CE

ENGINEERING SUPPORT & SERVICE CONTACTS:

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