



Declaration of Conformity

We, Oro Clean Chemie AG, declare under our sole responsibility that the medical device **OROLIN®** Burbath of class IIb meets all the provisions of Directive 93/42/EEC, which apply to it.

APPLIED NORMATIVE DOCUMENTS

ISO 9001, ISO 13485, ISO 14971, EN 1040, EN 1275, EN 13624, EN 13727, EN 14348, EN 14476, EN 14561, EN 14562, EN 14563, EN 14885, DGHM standard methods, RKI / DVV guidelines

CONFORMITY ASSESSMENT PROCEDURE

Annex II.3 of Directive 93/42/EEC

NOTIFIED BODY (IF CONSULTED)

SQS Schweizerische Vereinigung für
Qualitäts- & Managementsysteme
Postfach
3052 Zollikofen
Switzerland

CE MARK AFFIXED

CE
1250

Fehraltorf, 23.02.2015
Oro Clean Chemie AG

Ursula Suter
General Manager