



Declaration of Conformity

PROSEPT® Burs

We, Hygiene 360 AG, declare under our sole responsibility that the medical device PROSEPT® Burs of class IIb meets all the provisions of Directive 93/42/EEC, which apply to it.

Delivery Forms

| | |
|-----------|------------------|
| OD-811250 | 250 ml bottle |
| OD-061065 | 1 litre bottle |
| OD-061070 | 2 litre bottle |
| OD-061075 | 5 litre canister |

Applied normative documents

EN 14885, EN 13624, EN 13727, EN 14348, EN 14476, EN 14561, EN 14562, EN 14563, RKI / DVV guidelines, ISO 14971, ISO 13485, ISO 9001

Conformity assessment procedure

Annex II.3 of Directive 93/42/EEC

Notified body (if consulted)

SQS Schweizerische Vereinigung für
Qualitäts- & Managementsysteme
Postfach
3052 Zollikofen
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CE mark affixed

CE
1250

Pfäffikon ZH, 04.11.2019
Hygiene360 AG

Ursula Suter
General Manager