



HYGIENE360°

SWISS  MADE

Declaration of Conformity

PROSEPT® Spray

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

Applied normative documents

EN ISO 13485, EN ISO 14971, EN 14885, EN 13624, EN 13697, EN 13727, EN 14476, EN 14348, EN 14561, EN 14562, EN 14563, 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

Pfäffikon ZH, 27.09.2019
Hygiene360 AG

Oro Clean Chemie AG
Allmendstrasse 21
8320 Fehraltorf
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info@oroclean.com

Ursula Suter
General Manager





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Declaration of Conformity

PROSEPT® Fortis

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

Applied normative documents

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

Conformity assessment procedure

Annex II.3 of Directive 93/42/EEC

Notified body (if consulted)

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Ursula Suter
General Manager





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Declaration of Conformity

PROSEPT® Wipes

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

Applied normative documents

EN ISO 13485, EN ISO 14971, EN 14885, EN 13624, EN 13727, EN 14348, EN 14476, EN 16615, RKI / DVV guidelines

Conformity assessment procedure

Annex II.3 of Directive 93/42/EEC

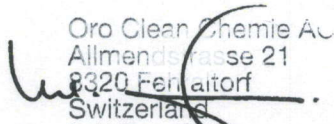
Notified body (if consulted)

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