

Declaration of Conformity

PROSEPT® Pera

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

Applied normative documents

EN 13727, EN 14347, EN 14348, EN 14476, ISO 14971, EN 14561, EN 14562, EN 14563, EN 14885, EN 1040, EN 1275, EN 13624, ISO 9001, ISO 13485, EN 13704

Conformity assessment procedure

Annex II.3 of Directive 93/42/EEC

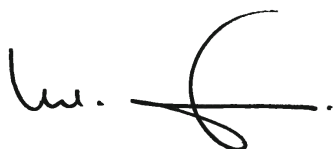
Notified body (if consulted)

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Qualitäts- & Managementsysteme
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Pfäffikon ZH, 21.06.2017
Hygiene360 AG



Ursula Suter
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