Declaration of Conformity

MANUFACTURER

Hygiene360 AG
Büelstrasse 17
8330 Pfäffikon ZH
Switzerland

AUTHORIZED REPRESENTATIVE

Hygiene360 s.r.o.
Vinohradská 2828/151
Žižkov
130 00 Prague 3
Czech Republic

IDENTIFICATION AND DESCRIPTION OF THE DEVICE

PROSEPT® Fortis (Powerful concentrate for the disinfection and cleaning of medical instruments through manual reprocessing):

Item Code	Trade Name	Description of Delivery Form
OD-060013	PROSEPT® Fortis	250 ml bottle
OD-060016	PROSEPT® Fortis	1 litre bottle with measuring cap
OD-060020	PROSEPT® Fortis	2 litre bottle with measuring cap
OD-060025	PROSEPT® Fortis	5 litre canister

RISK CLASS OF THE DEVICE

Class IIb (according to the classification rules in Annex IX of the Council Directive 93/42/EEC concerning medical devices)

CONFORMITY ASSESSMENT PROCEDURE

Annex II (excluding Section 4 of the Council Directive 93/42/EEC concerning medical devices)

STANDARDS APPLIED

EN ISO 13485:2016, EN ISO 14971:2019, ISO 10993-1:2018, EN 62366-1:2015, EN 14885:2018, EN ISO 21530:2004, EN 1041:2008+A1:2013, EN ISO 15223-1:2016

NOTIFIED BODY

DNV Product Assurance AS
Veritasveien 3
1363 Høvik
Norway

CE MARK AFFIXED

CE
2460

AUTHORIZED SIGNATORY

This Declaration of Conformity is issued under the sole responsibility of Hygiene360 AG. We hereby declare that the above-mentioned device(s) meet the provisions of the Council Directive 93/42/EEC concerning medical devices. This declaration is supported by the Quality System approval to EN ISO 13485, issued by DNV Product Assurance AS Notified Body Number 2460. All supporting documentation is retained at the premises of the manufacturer.

Digitally signed by
Juerg Suter
Date: 2021.04.07
16:46:38 +02'00'

Name: Juerg Suter
Designation: Chief Operating Officer
Place of Issue: Pfäffikon ZH
Date of Issue: 08.04.2021
Document Version: ADUR01

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