

CE Declaration of Conformity



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We, company

Steril Safety Products B.V.
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declare under sole responsibility, that our products

Wash check indicator

Artikelnr. 2.210.001 - 2.210.100 / HS-38220000

Formulation of the Wash check is based on tests soils stated on EN ISO 15883-5, concretely in annex G (for checking surgical instruments, rigid endoscopy, anaesthesia equipment and infant feeding bottles) and partially in annex P (bedpans and commode pans).

Annex G is a German soil text, with this content:

- Defibrinated sheep blood.
- Enterococcus faecium ATCC 6057
- Skimmed milk powder
- Butter
- Sugar
- Semolina (durum wheat meal)
- Tap water
- Egg yolk
- Casein peptone

These ingredients, jointly with an artificial red ink that demonstrates the removal of dirt.

The inclusion of the test soils and methods in EN ISO 15883-5 does not indicate that they are of equivalent sensitivity in their determination of cleaning efficacy.

Acceptance criteria are included, based on visual inspection and/or a microbiological end-point as stated for each method. Where chemical detection of residual soiling is required, methods can be complemented by the specific determination of a residual component of the applied test soil.

Any modifications to the device which are not authorized will invalidate this Declaration of Conformity.

Steril Safety Products B.V.

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Venlo-Blerick, The Netherlands
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