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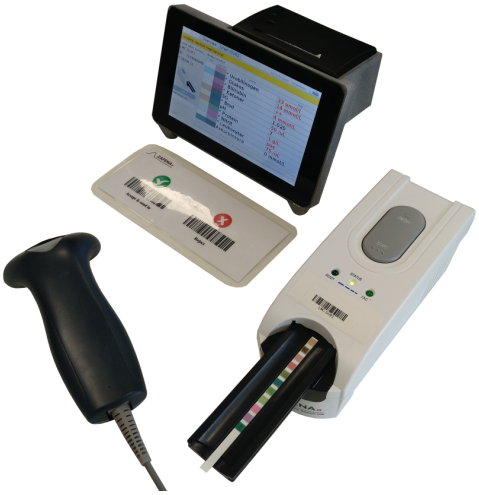
Simple Simon UA Plus
CE – Compliance to Directive 98/79 EC
In vitro diagnostic medical device



Simple Simon® UA Plus is classified as a general IVD product, class 1 and is compliant to Directive 98/79 EO, Annex 1.

The assessment of class I device is performed by the manufacturer himself. Responsibility for CE-marking in this category lies with the manufacturer who carries out internal checks to ensure that products meet the requirements.

Essential requirements

A. General requirements
Simple Simon® UA Plus meets general requirements, when used as intended; it achieves the performance intended by the manufacturer and meets high standards for the protection of life, personal safety and health of patients and others.

B. Design and manufacturing requirements
The IVD product Simple Simon® UA Plus is manufactured to meet high demands on analytic performance; this is secured through continuous quality assurance surveillance. Files on quality-control performance is kept at Zafena.

Annex 1, section 8.1 of the IVD Directive 98/79/EC requires manufactures, to supply the information necessary for the safe and proper use of the device.

A detailed Instructions For Use, IFU, and Product description is provided together with the product. Theses documents give information on safe and correct handling procedures and complies with requirements given in Directive 98/79 EC.

Labeling of the product is in compliance with the Directive.

Simple Simon® UA Plus urine analyzer is EMC tested and approved by an accredited laboratory.

Vigilance system

Vigilance reporting system in compliance to guidelines in MEDDEV 2.12/1 Rev 5 from the EU-commission are applicable to Simple Simon® UA Plus.
The product has a vigilance reporting system. An internal vigilance system is used to maintain a continuous quality control system and continuous improvement of the product.

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Mats Rånby
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