



Ängelholm December 3rd,2018

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Statement of Non-IVD Product of HemoCue® Cleaner

We, HemoCue® AB, hereby state that the product HemoCue® Cleaner is a general lab material that does not fall in the scope of EU IVD Directive 98/79/EC or EU Medical Device Directive 93/42/EEC. Therefore it should not be regarded as an IVD product or medical device.

The HemoCue® Cleaner being a general purpose lab material is non sterile, Non measuring with neither short term nor transient duration of use.

HemoCue® Cleaner are only used to clean the cuvette holder and Optronic unit as stipulated within the Instruction for User for each HemoCue Analyzers. As an alternative HemoCue also recommends the user to use a lint free cotton swab, non-pre-treated, moistened with alcohol (20-70% without additive). HemoCue Cleaner are not considered as In Vitro Diagnostic device accessories because they are not intended specifically by HemoCue AB to be used together with a device to enable HemoCue devices to be used in accordance with its intended purpose.

For and on behalf of HemoCue AB



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