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Att.: To whom it may concern

Ref:
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Init:
TWS

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Conformity Statement on the *Chemometec NucleoCassette™*, *SP1-Cassette™*, *SCC-Cassette™*, *PI-Cassette™*, *Via1-Cassette™* and *Via2-Cassette™*

This is a statement on the conformity of the *NucleoCassette™*, *SP1-Cassette™*, *SCC-Cassette™*, *PI-Cassette™*, *Via1-Cassette™* and *Via2-Cassette™* (hereafter referred to as: the Cassette) manufactured by Chemometec with current legislation regarding labelling obligations.

The Cassette is a custom-made disposable plastic device designed for optimal sample handling and safe disposal. It is preloaded with chemical reactants used for staining cells loaded from a sample mixture. The sample and the chemical reactants are fully contained within the Cassette and will not be released during use, and the Cassette including the sample can safely be disposed of after use.

Based on *Guidance on requirements for substances in articles (Version 4.0, June 2017)* published by the European Chemicals Agency (ECHA) and product descriptions provided by Chemometec* it is assessed that the Cassette with its content of chemical reactants is regarded as an article under Regulation 1907/2006 (REACH-regulation). Consequently, the Cassettes and their secondary packaging need not to be classified and labelled according to the CLP-regulation (Regulation No 1272/2008) and according to the REACH-regulation, a safety datasheet (SDS) for the chemical reactants is not required.

It should be noted that according to the above-mentioned REACH-regulation, manufacturers and importers must notify ECHA if an article contains a "substance of very high concern" (SVHC) at a concentration of 0.1% weight by weight and if the total manufacture/import quantity of this substance exceeds one tonne per year.

Sincerely,

09-03-2018

X 

Torben Wilde Schou, MSc, PhD
Scientific Advisor
Signed by: Torben Wilde Schou

* 992-0010 Package Insert for NucleoCassette
992-0100 Package Insert for SP1-Cassette
992-0201 Package Insert for SCC-Cassette
992-3001 Package Insert for Via1-Cassette
992-3003 Package Insert for PI-Cassette
992-3101 Package Insert for Via2-Cassette