

Addendum to the Declaration of Conformity

On behalf of MRC Holland, legal manufacturer of SALSA® MLPA® products and Cofflayser.Net analysis software, I hereby declare that all CE marked products covered by the Declaration of Conformity documents listed in Annex 1 under the Directive 98/79/EC will receive an up-classification under the EU2017/746 Regulation.

All products covered by this addendum will become Class C (various rules) IVD medical devices and will rely on the EU2017/746 Article 110(3) soft transition.

Jan Schouten

CEO

MRC Holland B.V.



Amsterdam, 24-08-2022

Annex 1

TD-DOC-01-Hhal Declaration of
Conformity

TD-DOC-01-MC002 Declaration of
Conformity

TD-DOC-01-ME011 Declaration of
Conformity

TD-DOC-01-ME028 Declaration of
Conformity

TD-DOC-01-ME032 Declaration of
Conformity

TD-DOC-01-P000 Declaration of
Conformity Reagent Kit

TD-DOC-01-P002 Declaration of
Conformity

TD-DOC-01-P003 Declaration of
Conformity

TD-DOC-01-P008 Declaration of
Conformity

TD-DOC-01-P015 Declaration of
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TD-DOC-01-P016 Declaration of
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TD-DOC-01-P017 Declaration of
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TD-DOC-01-P018 Declaration of
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TD-DOC-01-P021 Declaration of
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TD-DOC-01-P033 Declaration of
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TD-DOC-01-P034-P035 Declaration of
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TD-DOC-01-P036 Declaration of
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TD-DOC-01-P041-P042 Declaration of
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TD-DOC-01-P043 Declaration of
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TD-DOC-01-P044 Declaration of
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TD-DOC-01-P045 Declaration of
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TD-DOC-01-P046 Declaration of
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TD-DOC-01-P050 Declaration of
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TD-DOC-01-P051-P052 Declaration of
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TD-DOC-01-P056 Declaration of
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TD-DOC-01-P060 - Declaration of
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TD-DOC-01-P062 Declaration of
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TD-DOC-01-P064 Declaration of
Conformity

TD-DOC-01-P065-P066 Declaration of
Conformity

TD-DOC-01-P070 Declaration of
Conformity

TD-DOC-01-P072 Declaration of
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TD-DOC-01-P077 Declaration of
Conformity

TD-DOC-01-P081-P082 Declaration of
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TD-DOC-01-P083 Declaration of
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TD-DOC-01-P087 Declaration of
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TD-DOC-01-P088 Declaration of
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TD-DOC-01-P090 Declaration of
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TD-DOC-01-P091 Declaration of
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TD-DOC-01-P093 Declaration of
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TD-DOC-01-P095 Declaration of
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TD-DOC-01-P101 Declaration of
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TD-DOC-01-P102 Declaration of
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TD-DOC-01-P114 Declaration of
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TD-DOC-01-P124 Declaration of
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TD-DOC-01-P137 Declaration of
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TD-DOC-01-P138 Declaration of
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TD-DOC-01-P140 Declaration of
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TD-DOC-01-P155 Declaration of
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TD-DOC-01-P158 Declaration of
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TD-DOC-01-P159 Declaration of
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TD-DOC-01-P163 Declaration of
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TD-DOC-01-P165 Declaration of
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TD-DOC-01-P178 Declaration of
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TD-DOC-01-P189 Declaration of
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TD-DOC-01-P190 Declaration of
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TD-DOC-01-P213 Declaration of
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TD-DOC-01-P225 Declaration of
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TD-DOC-01-P226 Declaration of
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TD-DOC-01-P236 Declaration of
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TD-DOC-01-P241 Declaration of
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TD-DOC-01-P244 Declaration of
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TD-DOC-01-P245 Declaration of
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TD-DOC-01-P248 Declaration of
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TD-DOC-01-P250 Declaration of
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TD-DOC-01-P256 Declaration of
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TD-DOC-03-P000-SD083 -
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TD-DOC-01-P260 Declaration of
Conformity

TD-DOC-03-P003-SD052 -
Declaration of Conformity

TD-DOC-01-P335 Declaration of
Conformity

TD-DOC-03-P088-SD079 -
Declaration of Conformity

TD-DOC-01-P337 Declaration of
Conformity

TD-DOC-03-P140-SD031 - Declaration
of Conformity

TD-DOC-01-P351-P352 Declaration of
Conformity

TD-DOC-03-P190-SD078 - Declaration
of Conformity

TD-DOC-01-P378 Declaration of
Conformity

TD-DOC-03-P256-SD032 - Declaration
of Conformity

TD-DOC-01-P405 Declaration of
Conformity

TD-DOC-03-P460-SD084 -
Declaration of Conformity

TD-DOC-01-P438 Declaration of
Conformity

TD-DOC-01-P461 Declaration of
Conformity

TD-DOC-01-SD039 Declaration of
Conformity

TD-DOC-01-SD072 Declaration of
Conformity

TD-DOC-01-SD089 Declaration of
Conformity

TD-DOC-03-ME011-SD086 -
Declaration of Conformity

TD-DOC-03-P000 - Declaration of
Conformity Coffalsyer.Net

TD-DOC-03-P000-SD022 -
Declaration of Conformity

TD-DOC-03-P000-SD067 -
Declaration of Conformity