

DECLARATION OF CONFORMITY

In vitro diagnostic medical devices

We hereby declare that the distributed CE marked products conform to the required technical documentation, in accordance with Annex III of the "EC-Directive", the Council Directive 98/79/EC of 27 October 1998, concerning in vitro diagnostic medical devices.

In addition, we ensure and declare that the distributed CE marked products meet the provisions of the EC-Directive which apply to them.

This Declaration of Conformity covers

SALSA® MC002 SMA Newborn Screen

as specified in the product list belonging to this declaration (see TD-DOC-02-MC002 Annex Declaration of Conformity), and is valid for all products concerned bearing the CE marking and manufactured at the following site:

Legal manufacturer

MRC-Holland b.v.
Willem Schoutenstraat 1
1057 DL Amsterdam
The Netherlands

Amsterdam, 10-10-2018

Signature

Dr. J.P. Schouten
CEO of MRC-Holland b.v.

