



DET NORSKE VERITAS AS

STATEMENT OF COMPLIANCE

Application of: Council Directive 98/79/EC-Invitro Diagnostic Devices- of 27 October 1998, issued as by the European Parliament and the Council of the European Union

STATEMENT NO. DNV—2010-IND-IVD-111001
(The statement consists of front page and Appendix)

The manufacturing of the following Equipment

FIBRAN 20

Manufactured by
SM Diagnostics

at

No.2, Neelakandan Street, Choolaimedu, Chennai – 600 094, Tamil Nadu, India

is found to comply with the requirements applicable to it

The manufacturer's technical Construction File (TCF), has been reviewed and found to comply with the requirements in Annex I of the **Invitro Diagnostic Devices Directive 98/79/EC**

Further identification, description of the products & conditions covered by this Statement are given in the Appendix-1.

Applications/Limitations:

Modifications made to the products shall immediately be reported to Det Norske Veritas in order to examine whether this Statement remains valid.

Place and date

Chennai 2010.06.17
DET NORSKE VERITAS REGION INDIA

This Statement is valid until

2013.06.08



Original Certificate Issue Date
2004-06-08

Bhupalam Ajit
Head – Technical (India & Sri Lanka)

Notice: The statement is subject to terms and condition, if any, overleaf. Any significant changes in design or construction of the product, the quality system or amendments to the Directive or Standards referenced above may render this statement invalid. The product liability rests with the manufacturer or his representative in accordance with the Council Directive, as amended.

It is agreed that save as provided below, Det Norske Veritas, its subsidiaries, bodies, officers, directors, employees and agents shall have no liability for any loss, damage or expense allegedly caused directly or indirectly by their mistake or negligence, breach of warranty, or any other act, omission or error by them, including gross negligence or wilful misconduct by any such person with the exception of gross negligence or wilful misconduct by the governing bodies or senior executive officers of Det Norske Veritas. This applies regardless of whether the loss, damage or expense has affected anyone with whom Det Norske Veritas has a contract or a third party who has acted or relied on decisions made or information given by or on behalf of Det Norske Veritas. * However, if any person uses the services of Det Norske Veritas or its subsidiaries or relies on any decision made or information given by or on behalf of them and in consequence suffers a loss, damage or expense proved to be due to their negligence, omission or default, then Det Norske Veritas will pay by way of compensation to such person a sum representing his proved loss. * In the event Det Norske Veritas or its subsidiaries may be held liable in accordance with the sections above, the amount of compensation shall under no circumstances exceed the amount of the fee, if any, charged for that particular service, decision, advice or information. * Under no circumstances whatsoever shall the individual or individuals who have personally caused the loss, damage or expense be held liable. * In the event that any provision in this section shall be invalid under the law of any jurisdiction, the validity of the remaining provisions shall not in any way be affected.

STATEMENT OF COMPLIANCE APPENDIX – 1

Appendix to Statement of Compliance No.: DNV—2010-IND-IVD-111001

Manufacturer: SM Diagnostics, India

Equipment: COAGULATION ANALYSER

Models : FIBRAN 20

Identification: 1. TCF / Drawing List as per Issue No.1.2 / Dated: 12.05.10
 2. Unique Serial Number for each product

Description of the equipment: The analyser is based on the Opto-mechanical principle and requires only once-a- day calibration.This is a micro volume coagulation testing with a reduced amount of reagent required for the test. The reagents have been standardised to provide international normalised ratios. The analyser incorporates programmable devices to enable updating Fibrinogen parameters.

Technical Documentation: TCF / Issue No.1.2 / Dated 12.05.10

European Representative Name and Address:

Mr. Franco Alunni

ASSEL Sri, Via E.Baranti 8,

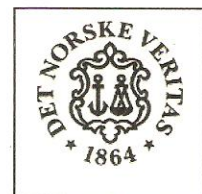
00012 Guidonia Roma, Italy

Tel. 0039 774 357 492 e. Mail: alunnif@asselitaly.eu

.Place and date
Chennai, 2010-06-17

A handwritten signature in blue ink, appearing to read 'Bhupalam Ajit', is written over a horizontal line.

Bhupalam Ajit
HEAD - Technical(India & Sri Lanka).



STATEMENT OF COMPLIANCE APPENDIX – 1

Appendix to Statement of Compliance No.: DNV—2010-IND-IVD-111001

Manufacturer: **SM Diagnostics, India**

Equipment: **COAGULATION ANALYSER**

Models : **FIBRAN 20**

Conditions:

1. The Technical construction file reviewed for the equipment listed above only. Refer Technical file for details. Design Examination is not considered since the product does not fall under List - A of Annexure II of the Directive. For other equipment & ranges, an application for extension of the statement must be sent to the local DNV Office.
2. This statement will remain valid only if Quality System Certificate remains valid and the surveillance audits are conducted. In the event the surveillance audit is not accepted within the one month of the notification date, the Statement of Compliance will be invalid.
3. The local DNV Office must be informed about any changes/ modification carried out to the equipment/ or Quality System. The Manufacturer must give information of any intended adjustments of the equipment / Quality system / specification to Det Norske Veritas AS, who will assess the changes and decide if the statement remains valid.
4. Before the above described equipments are placed on the market and / or put into use the manufacturer has to ensure that all other relevant Directive are complied with.

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.Place and date
Chennai, 2010-06-17

A handwritten signature in blue ink, appearing to read 'Bhupalam Ajit', is written over a horizontal line.

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