MANUFACTURER'S DECLARATION OF CONFORMITY

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 27 October 1998
on in vitro diagnostic medical devices as corrected and amended up to 30.10.2003

This is a declaration made in accordance with the provisions of DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on *in vitro diagnostic medical devices.*

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Manufacturer	*Vela Operations Singapore Pte. Ltd,* *#05-07 The Kendall, 50 Science Park Road, Singapore 117406.*
European Authorised Representative	*Vela Diagnostics Germany GmbH,* *Albert-Einstein-Ring 15,* *22761 Hamburg,* *Germany.*

IVD Medical Device(s):

Item No.	Name of Device	Classification	EDMA/GIVD Code		EDMA and GIVD Name
300678	ViroKey™ SX Virus Total Nucleic Acid Kit	General IVD (Non List A/B and Non self-testing)	EDMA / GIVD	15.90.40.01	Reagents for DNA and/or RNA extraction and preparation: bacteria and/or virus

Scope of Application: *All above listed products to which the approved quality management systems have been applied*

Each kind of IVD medical device to which the manufacturer's quality management systems have been applied complies with the requirements of Annex I, Essential Requirements of the directive, at each stage from the design of the device until its final inspection before being supplied. In addition, the harmonised standards listed in the attachment to this declaration of conformity were applied to meet the essential requirements.

This declaration is being made in accordance with Annex III, having prepared the technical documentation described in Annex III, and implemented a Quality Management System that is compliant with *EN ISO 13485: 2016* hence fulfilling Annex III, sections 4 and 5 requirements.

Authorised Signatory

2020-06-22

Signature ***Date***

Boon King TEH — Head, QARA

Name ***Position***

Attachment to Manufacturer's Declaration of Conformity for ViroKey™ SX Virus Total Nucleic Acid Kit – List of Applied European harmonised standards to conform to the Essential Requirements

Standard Number	Name of Standards
EN ISO 13485: 2016	*Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)*
EN 13612: 2002/AC: 2002	*Performance evaluation of in vitro diagnostic medical devices*
EN ISO 14971: 2012	*Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)*
EN ISO 15223-1:2016	*Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)*
EN ISO 18113-1: 2011	*In vitro diagnostic medical devices -- Information supplied by the manufacturer (labelling) -- Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)*
EN ISO 18113-2: 2011	*In vitro diagnostic medical devices -- Information supplied by the manufacturer (labelling) -- Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)*
EN 62366:2008	*Medical devices - Application of usability engineering to medical devices*