January 28, 2022

DECLARATION OF CONFORMITY

We, Siemens Healthcare Diagnostics Inc. located 500 GBC DR, PO Box 6101, Newark, DE 19714, USA as the product owner, hereby declares that the medical device listed below complies to list of applied standards in Annex 1 (attached)

No.	SMN code	REF	Product description
1	10445041	DSC4	Dimension/ Dimension Vista Sample Cups
2	10445570	STM1	Dimension Sample Transfer Module Pipette Tips
3	10445044	RXV1A	Dimension Reaction Vessels

For and on behalf of Siemens Healthcare Diagnostics Inc.,

Nathani Anusha

Digitally signed by Nathani Anusha
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Anusha Nathani
Regulatory Affairs Professional

Annex 1: List of Standards Applied:

Standards Cited in Annex I	Standard Name	Current Revision Level
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2018	2016/AC:2018
EN 13612	Performance evaluation of in vitro diagnostic medical devices	2002/AC:2002
EN ISO 14971	Medical Devices- Application of risk management to medical devices (ISO 14971:2007; corrected version 2007-10-01)	2012
EN ISO 15223 - 1	Medical Devices- Symbols to be used with medical device labels, labeling, and information to be supplied—Part 1: General requirements (ISO 15223-1:2016, Corrected version 2016-12-15)	2016
EN ISO 18113-1	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)	2011
EN ISO 18113-3	In vitro diagnostic medical devices -- Information supplied by the manufacturer (labelling) -- Part 3: In vitro diagnostic instruments for professional use	2011
EN 62366	Medical Devices – Application of usability engineering to medical devices (IEC 62366:2007)	2008
IEC 62366-1	Medical devices – Part 1: Application of usability engineering to medical devices	2015

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