

### To whom it may concern

We, **Siemens Healthcare Private Limited** having manufacturing facility at E-14 & 15 Manjusar GIDC, Savli, Vadodara, Gujarat, 391776, India as the product owner, hereby declares that the medical devices mentioned in Annex 1 comply to the below standards

#### List of Standards Applied:

Standards Cited in Annex 1	Standards Name
EN 375: 2001	Information supplied by the manufacturer with in vitro diagnostic reagents for Professional Use-testing.
EN 591:2001	Instructions for use for in vitro diagnostic instruments for Professional Use-testing.
EN 980: 2008	Graphical symbols for use in the labeling of medical devices
EN12286:1998/A1:2000	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Presentation of reference measurement procedures
EN 12287:1999	In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Description of reference materials
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 13532: 2002	General requirements for in vitro diagnostic medical devices for self-testing
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
EN 13640: 2002	Stability Testing of In vitro Diagnostic reagent
EN 13641: 2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN 13975:2003	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspects
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007)
EN 62366:2015	Medical Devices-Application of Usability Engineering to Medical Device

For and on behalf of Siemens Healthcare Private Limited

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Name: Shripad Panvalkar

Manager Quality Assurance

## Annex 1

Product Code	REF Code	Product Name
109741467	ALB-701	AUTOPAK Albumin
110667152	ALP-715	AUTOPAK Alkaline Phosphatase AMP
109741470	ALP-705	AUTOPAK Alkaline Phosphatase
109741517	AMY-901	AUTOPAK Amylase-Liquid Stable
110709024	ADA-621	AUTOPAK Adenosine Deaminase
110709023	ASO-631	AUTOPAK Anti-Streptolysin O
110667159	D.BIL-726	AUTOPAK Direct Bilirubin
110667158	T.BIL-724	AUTOPAK Total Bilirubin
109741471	BUN-904	AUTOPAK BUN
109741518	CHO-802	AUTOPAK Liquid Cholesterol
109741468	CRT-703	AUTOPAK Creatinine
110308190	CRT-713	AUTOPAK Creatinine
110709025	CRP-641	AUTOPAK C-Reactive Protein
109741472	CK-905	AUTOPAK CK
110667153	CAL-740	AUTOPAK Calcium ARS
109741520	HDL-601	AUTOPAK Liquid Direct HDL
109741557	LDL-611	AUTOPAK Liquid Direct LDL
110667157	GLU-677	AUTOPAK Glucose HEXO
109741474	GLU-702	AUTOPAK Glucose (Tablet format)
109741558	GGT-907	AUTOPAK GGTP- Liquid Stable
110667160	IRON-671	AUTOPAK IRON
110661434	LIP-651	AUTOPAK Lipase
110667154	MG-675	AUTOPAK Magnesium
109741469	PHO-704	AUTOPAK Inorganic Phosphorus
110661423	RF-661	AUTOPAK Rheumatoid Factor
109741514	AST-902	AUTOPAK SGOT (AST)
109741515	ALT-903	AUTOPAK SGPT (ALT)
110667155	TPR-786	AUTOPAK Total Protein Mono
109741519	TRI-803	AUTOPAK Liquid Triglycerides
109741516	URI-801	AUTOPAK Uric acid
110667161	UIBC-794	AUTOPAK UIBC FERENE
109741564	N/A	ADA Calibrator
109741565	N/A	ASO Calibrator
109741566	N/A	CRP Calibrator
109612202	N/A	HDL- Calibrator
109612200	N/A	LDL- Calibrator
109612203	N/A	Multi Calibrator