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IEC62304:2006 Declaration of Conformity of enAble X1 Delivery 1.0.3

Curtis Instruments AG confirms that the software development and maintenance of the generic enAble X1 system meets the intent of IEC62304:2006, and is based on a layered V-model approach.

The enAble X1 system meets the requirements of functional safety, as far as applicable.

The declaration of conformity is valid for the following modules main and application software:

Device	Model-No.	HW Version	Main Appl.
PB120-E	1760-3501	4 / 5	05.046.003
HCS	1761-25x1	2	05.071.000
DM	1763-1401	2	05.071.000
AC	1762-1101	1	05.060.000
AAM	1764-5001	1 / 2	05.046.006
AAM2L	1765-2101	2	
AM3L / AM3	1765-5x01	1 / 2	05.046.003
LML	1765-0201	1	
ESM	1768-4x01	1	05.046.003
SCIM/ SPM	1767-x001	2	05.046.003

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