

Manufacturer	Declaration of Conformity	Document ref.: DOC-Rev 21.0
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DECLARATION OF CONFORMITY

- 1) **Manufacturer:** **Med X Change Inc.**

Address:

417 8th Street West
Bradenton, FL 34205, USA

and

- 2) **European authorized representative:** **AJW Technology Consulting GmbH**

Address:

Königsallee 106,
40215 Düsseldorf,
Germany

- 3) **Product(s) (name, type or model, etc.):**

Digital Recording Systems – **Evolution4K**

- 4) **"UMDNS Code":** **15595 – Recorders**

- 5) **"GMDN Code":** **18034 – Endoscopic Video Image Processor**

- 6) The product(s) described above are in conformity with:

<u>Document No.</u>	<u>Title</u>	<u>Edition / Date of Issue</u>
2014/35/EU	Low Voltage Directive	April 2016
2016/679	European General Data Protection Regulation (EU)	2016
2004/108/EC	EMC Directive	31Dec2004
EN 60601-1-2	Medical Electrical Equipment	2014/AC:2010
CAN/CSA-C22.2 NO. 60601-1-2-08	General Requirements – Canadian Electrical Code, Part II	R2014
ISO 7000	Graphical Symbols for use on equipment – Index and synopsis	2014

- 7) **Additional information:**

We, the manufacturer, hereby declare that the devices listed above conform to the applicable standards identified above, and the provisions of Low Voltage Directive 2014/35/EU. The conformity has been assessed according to the procedure detailed in Annex IV of the same Low Voltage Directive 2014/35/EU.

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This Declaration of Conformity is valid 5 years from issue date.


 Edwin Martinez / Director of QA & RA

Date

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Appendix A

Date: 2018-12-18

List of devices.

Device name	Type/model/ref number	First date of CE-marking
Digital Recording System	Evolution4K	2017-12-29