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Technical Documentation for [medical device]	/	Commented [AES1]: Include the name of the medical device or medical device group for which this Technical Documentation is prepared.
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Document information

Version:	0.1
Created by:	
Approved by:	
Date of version:	

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Change history

Date	Version	Created by	Description of change

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Technical Documentation

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1.3. Device description	Commented [AES11]: Make a list of all versions, dimensions
Description of device	Commented [AES12]: List: •An overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist;
Set of all services and diversions.	Commented [AES13]: Provide the exact description of the intended purpose as described in the device's IFU.
Reference to previous and ornine generations of the decod	In exceptional cases where an instruction for use is not required, describe the generally recognized modalities of use, including: •name of disease or condition, clinical form, stage, severity

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Intended use/purpose in alignment with Instructions for Use (IFU)

1.4.

Intended purpose

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We herewith declare that the abovementioned products meet the provisions of the following EC Council Medical Device Regulation 2017/745 and its implementation in national law. All supporting documentation is retained on the premises of the manufacturer.	7/	Commented [AES23]: Include the list of applicable harmonize
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