


## RED Declaration of Conformity

Abbott Medical hereby declares that the following product(s) conform to the applicable provisions of the Radio Equipment Directive (2014/53/EU). All supporting documentation is retained under the premises of Abbott Medical. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

<b>Manufacturer Address:</b>	Abbott Medical, 15900 Valley View Court, Sylmar, CA 91342, USA
<b>European Representative</b>	Abbott Medical, The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Belgium
<b>Product Type:</b>	Implantable Pacemakers
<b>Applicable Standards:</b>	3.1a: EN 62311:2008, EN45502-1:2015, EN 45502-2-1:2003, ISO 14708-1:2014, ISO 14708-2:2012  3.1b: 45502-2-1:2003, EN 60601-1-2:2015, ISO14117:2019, EN 301 489-1 V2.1.1 (2017-02), EN 301 489-31 V2.2.1 (2019-04),  3.2: EN 302 195 V2.1.1 (2016-06)
<b>Applicable Annex:</b>	II
<b>Technical Construction File:</b>	60085289
<b>Signature:</b>	
 _____ Umesh Shah Director, Development Quality	<u>13 - Dec - 2023</u> Issue Date

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Product Name (s)	Model #	Description of accessories and components:
Endurity™ Core	PM1152	The Abbott pacemakers are implantable pulse generators that, when used in combination with compatible pacing leads, are intended to detect and treat chronic symptomatic bradyarrhythmia and various atrioventricular conduction abnormalities by providing sensing and pacing in the ventricle(s) and/or right atrium.
Endurity™ Core	PM2140	
Endurity™ Core	PM1140	
Endurity™ Core	PM2152	
Endurity™	PM1162	
Endurity MRI™	PM1172	
Endurity™	PM2162	
Endurity MRI™	PM2172	
Zenex MRI™	PM1182	
Zenex MRI™	PM2182	