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).

Manufacturer Address:	Abbott Medical, 15900 Valley View Court, Sylmar, CA 91342, USA
European Representative	Abbott Medical, The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Belgium
Product Type:	Implantable Pacemakers
Applicable Standards:	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), EN 301 489-17 V3.2.4(2020-09), EN 301 489-27 V2.2.1 (2019-04) 3.2: EN 302 195 V2.1.1 (2016-06) EN 300 328 V2.2.2 (2016-11)
Applicable Annex:	II
Technical Construction File:	60085296

Signature:

Umesh S. Shah

Umesh Shah
Director, Development Quality

13-Dec-2023
Issue Date

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Product Name (s)	Model #	Description of accessories and components:
Assurity MRI™ Assurity MRI™	PM1272 PM2272	**Pacemakers** 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.
Zenex MRI™ Zenex MRI™	PM2282 PM1282	
Allure™ RF Quadra Allure™ Quadra Allure MP™ RF Quadra Allure MP™	PM3222 PM3542 PM3262 PM3562	**CRT-P's** CRT-P devices are intended to resynchronize the right and left ventricles via biventricular pacing.