

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 Cardioverter Defibrillators
Cardiac Resynchronization Therapy – Defibrillators


Applicable Standards: 3.1a:
EN 62479:2010, EN 45502-1:2015, EN 45502-2-2:2008,
ISO 14708-1:2014, ISO 14708-6:2019

3.1b:
EN 45502-2-2:2008, 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)

3.2:
EN 302 195 V2.1.1 (2016-06)
EN 300 328 V2.2.2 (2019-07)

Applicable Annex: II

Technical Construction File: 90661040

Signature:


Umesh Shah
Director, Development Quality

20-June-2023
Issue Date

RED Declaration of Conformity

Product Name (s)	Model #	Description of accessories and components:	
Entrant™ VR	CDVRA300Q	The Implantable Cardioverter Defibrillator (ICD) devices and Cardiac Resynchronization Therapy Defibrillator (CRT-D) devices are primarily intended for use with compatible leads to detect and treat life threatening ventricular arrhythmias by providing ventricular antitachycardia pacing, and ventricular cardioversion/defibrillation. In addition, these devices can detect and treat chronic symptomatic bradyarrhythmia by providing sensing and pacing in the right ventricle, and various atrioventricular conduction abnormalities by providing sensing and pacing in the right ventricle and/or the right atrium.	
Entrant™ DR	CDDRA300Q		
Entrant™ HF	CDHFA300Q		
Gallant™ VR	CDVRA500Q		
Gallant™ DR	CDDRA500Q		
Gallant™ HF	CDHFA500Q		
Neutrino™ NxT VR	CDVRA600Q		
Neutrino™ NxT DR	CDDRA600Q		
Neutrino™ NxT HF	CDHFA600Q		
Avant™ VR	CDVRA700Q		
Avant™ DR	CDDRA700Q		
Avant™ HF	CDHFA700Q		
Neutrino™ NxT VR	CDVRA800Q		CRT-D devices sense cardiac activity and provide pacing to resynchronize the right and left ventricles
Neutrino™ NxT DR	CDDRA800Q		
Neutrino™ NxT HF	CDHFA800Q		