

MDCG 2021-11

Guidance on Implant Card – ‘Device types’

May 2021

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and a representative of the European Commission chairs it.

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Implant Card – ‘Device types’

Article 18 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR)

Version 1.1

According to Article 18 (a) of the MDR, the manufacturer of an implantable medical device shall provide together with the device, **information allowing the identification of the device**, including the **device name**, serial number, lot number, the UDI, the device model, as well as the name, address and the website of the manufacturer.

In accordance with the instructions laid out in [MDCG 2019-8](#), the implant card should also indicate a ‘device type’ for the implantable medical device in question (see in red below).


en Pacemaker / bg пейсмейкър / cs Kardiostimulátor / da Pacemaker /
de Schrittmacher / el Βηματοδότης / es Marcapasos / et Südamestimulaator /
fi sydämentahdistin / fr Stimulateur cardiaque / hr Pejsmejker /
hu Pacemaker / it Stimolatore cardiaco / is Gangráður / lt širdies
stimuliatorius / lv Elektrokardiostimulatori / nl Pacemaker / no pacemaker /
pl Rozrusznik serca / pt-pt Marcapasso/ ro pacemaker / sk kardiostimulátor /
sl Srčni spodbujevalnik / sv Pacemaker

MD

PM-5503Pacer Advanced


UDI-DI: (01)01865494261654

UDI



SN

SN79856214

Genericmed
500 Genericmed Place, Minneapolis, MN 55123 USA
www.genericmed.com

As such, this document provides a non-exhaustive list of implantable medical ‘device types’ in order to aid manufacturers in allocating an appropriate term for this requested information.

A balance between the information a patient and a healthcare professional require was a main driver behind the suggested ‘device types’.

This document will be updated, as appropriate, and following the agreement of the MDCG.

Medical Devices

#	Implantable Medical Device	Implantable Medical 'Device type'	Publication
1.	Implantable cardiac pacemaker	Pacemaker	Version 1.1
2.	Implantable cardiac leadless pacemaker	Leadless pacemaker	Version 1.1
3.	Implantable cardiac monitor	Cardiac monitor	Version 1.1
4.	Implantable cardiac defibrillator	Defibrillator	Version 1.1
5.	Cardiac lead	Cardiac lead	Version 1.1
6.	Pacemaker ICD Lead	Pacemaker ICD lead	Version 1.1
7.	Neural lead	Neural lead	Version 1.1
8.	Spinal Neural stimulator	Spinal stimulator	Version 1.1
9.	Brain Neural stimulator	Brain stimulator	Version 1.1
10.	Implantable pump	Medicinal pump	Version 1.1
11.	Cranial shunt	Brain shunt	Version 1.1
12.	CSF shunt	CSF shunt	Version 1.1
13.	Lumbar shunt	Lumbar shunt	Version 1.1
14.	Hydrocephalus valve implant	Brain valve	Version 1.1
15.	CSF Valve	CSF Valve	Version 1.1
16.	Lumbar valve	Lumbar valve	Version 1.1
17.	Cranio-facial reconstruction Implant	Craniofacial implant	Version 1.1
18.	Dura patch	Dura patch	Version 1.1
19.	Intraocular lens	Intraocular lens	Version 1.1
20.	Ophthalmic filtration drain	Glaucoma drain	Version 1.1
21.	Ophthalmic liquid	Ophthalmic liquid	Version 1.1
22.	Mechanical aortic valve	Mech. Aortic Valve	Version 1.1

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23.	Mechanical mitral valve	Mech. Mitral Valve	Version 1.1
24.	Mitral valve bio prosthesis	Bio. Mitral valve	Version 1.1
25.	Pulmonary valve bio prosthesis	Bio. Pulmonary valve	Version 1.1
26.	Valved graft	Valved graft	Version 1.1
27.	Left atrial appendage closure	Atrial closure	Version 1.1
28.	Neurovascular coil	Neurovascular coil	Version 1.1
29.	Neurovascular stent	Neurovascular stent	Version 1.1
30.	Neurovascular flow diverter	Neurovascular stent	Version 1.1
31.	Mitral annuloplasty ring	Mitral ring	Version 1.1
32.	Annuloplasty band	Annuloplasty band	Version 1.1
33.	Vascular patch	Vascular patch	Version 1.1
34.	Vascular plug	Vascular plug	Version 1.1
35.	Aortic valve bio prosthesis	Bio. Aortic valve	Version 1.1
36.	PFO-Occluder	PFO Occluder	Version 1.1
37.	Aortic stent graft	Aortic stent graft	Version 1.1
38.	Aortic anchor	Aortic anchor	Version 1.1
39.	Oesophageal stent	Oesophageal stent	Version 1.1
40.	Enteral stent	Enteral stent	Version 1.1
41.	Biliary stent	Biliary stent	Version 1.1
42.	Tracheobronchial stent	Tracheobronchial stent	Version 1.1
43.	Pancreatic stent	Pancreatic stent	Version 1.1
44.	Renal stent	Renal stent	Version 1.1
45.	Endoscopic drainage stent	Drainage stent	Version 1.1

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46.	Coronary stent	Coronary stent	Version 1.1
47.	Self-expanding peripheral stent	Peripheral stent	Version 1.1
48.	Balloon expandable peripheral stent	Peripheral stent	Version 1.1
49.	Venous stent	Venous stent	Version 1.1
50.	Hip joint replacement	Hip implant	Version 1.1
51.	Knee joint replacement	Knee implant	Version 1.1
52.	Shoulder joint replacement	Shoulder implant	Version 1.1
53.	Elbow replacement system	Elbow implant	Version 1.1
54.	Hand joint replacement	Hand implant	Version 1.1
55.	Wrist implant	Wrist implant	Version 1.1
56.	Extremity replacement component	Ankle implant	Version 1.1
57.	Extremity replacement component	Foot implant	Version 1.1
58.	Spinal stent	Spinal stent	Version 1.1
59.	Spinal fusion device	Spinal fusion	Version 1.1
60.	Spinal fixation system	Spinal fixation	Version 1.1
61.	Spinal stabilisation system	Spinal stabiliser	Version 1.1
62.	Anchor	Bone anchor	Version 1.1
63.	Bone nailing implant	Bone nail	Version 1.1
64.	Bone distraction device	Bone distraction	Version 1.1
65.	Cranial clamp	Cranial clamp	Version 1.1
66.	Bone cement	Bone cement	Version 1.1
67.	Bone wax	Bone wax	Version 1.1
68.	Bone plug	Bone plug	Version 1.1

Medical Devices

69.	Hernia mesh	Hernia mesh	Version 1.1
70.	Flexible plate	Tissue plate	Version 1.1
71.	Breast implant	Breast implant	Version 1.1
72.	Intraperitoneal port	Intraperitoneal port	Version 1.1
73.	Vein adhesive	Vein adhesive	Version 1.1
74.	Absorbable haemostats	Absorbable haemostats	Version 1.1
75.	Ureteral bypass	Ureteral bypass	Version 1.1
76.	Urinary incontinence - injectable bulking agent	Bladder implant	Version 1.1
77.	Ureteral stent	Ureteral stent	Version 1.1
78.	Enteral feeding devices	Enteral feeding	Version 1.1
79.	Fiducial marker	Fiducial marker	Version 1.1
80.	Embolic coils	Embolic coil	Version 1.1
81.	Embolic beads	Embolic bead	Version 1.1
82.	Embolic particles	Embolic particles	Version 1.1
83.	Prostatic implant	Prostatic implant	Version 1.1
84.	Urinary incontinence sling	Incontinence sling	Version 1.1
85.	Pelvic organ prolapse mesh	Pelvic mesh	Version 1.1
86.	Testicular prosthesis - saline-filled	Testicular prosthesis	Version 1.1
87.	Septal Patch	Heart patch	Version 1.1
88.	Gastric Band	Gastric band	Version 1.1