



DGK.

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Stellungnahme der Deutschen Gesellschaft für Kardiologie - Herz- und Kreislaufforschung e.V. zur Anfrage der Europäischen Kommission nach Evidenzen für etablierte Technologien gemäß Art. 52(4), Unterabsatz 2, and Art. 61(6)(b) MDR

Düsseldorf, 17 January 2025

List of well-established technologies (WET) in Cardiology

with reference to the request for evidence on well-established technologies as referred to in Article 52(4), second sub-paragraph, and Article 61(6)(b) MDR

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| | Organisation: | Deutsche Gesellschaft für Kardiologie - Herz- und Kreislaufforschung e.V. German Cardiac Society Working group of arrhythmias (AGEP) Working group of interventional cardiology (AGIK) |
| 1 | Name of technology | Ablation catheters using radiofrequency or cryo energy |
| | Short description of technology | <i>Transvenously inserted catheters to apply radiofrequency or cryo energy for the treatment cardiac arrhythmias</i> |
| | Justification why WET | <i>Ablation catheters are used for the treatment of cardiac arrhythmias for over 30 years. There is ongoing development of existing devices and new devices. However, there are specific catheters on the market, which are used for more than 5 (up to 15) years without or only minor modification and without any safety issues. They have well-known clinical performance characteristics and are used as standard of care.</i> |
| | Examples of devices falling under the category, including the risk class and classification rule used | <i>Irrigated radiofrequency ablation catheters (class III, rule 6), non-irrigated radiofrequency ablation catheter (class III, rule 6), cryo single-tip ablation catheters (class III, rule 6), cryo balloon ablation catheter (class III, rule 6).</i> |
| 2 | Name of technology | Diagnostic electrophysiological catheters |
| | Short description of technology | <i>Transvenously inserted catheters, positioned in the heart with the ability to record electrical cardiac signals and to pace the heart for the classification and diagnosis of cardiac arrhythmias</i> |
| | Justification why WET | <i>Diagnostic electrophysiological catheters are used for diagnosing of cardiac arrhythmias for over 30 years. There is ongoing development of existing devices and new devices. However, there are specific diagnostic catheters on the market, which are used for more than 5 (up to 20) years without or only minor modification and without any safety issues. They have well-known</i> |

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| | | <i>clinical performance characteristics and are used as standard of care.</i> |
| | Examples of devices falling under the category, including the risk class and classification rule used | <i>Steerable diagnostic catheters (class III, rule 6), non-steerable diagnostic catheters (class III, rule 6), spiral diagnostic catheters (class III, rule 6), high-density mapping catheters (class III, rule 6)</i> |
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| 3 | Name of technology | Leads for cardiac pacing and defibrillation |
| | Short description of technology | <i>Transvenously implanted leads and positioned in cardiac chambers (right atrium, right ventricle, coronary sinus) connected to cardiac implantable electronic devices(CIED) for cardiac pacing and defibrillation.</i> |
| | Justification why WET | <i>Cardiac pacing and defibrillation via CIED is performed for 40 years. There is continuous development in lead technology. However, there are specific pacing and defibrillation leads on the market, which are used for more than 5-10 years without or only minor modification and without any safety issues. They have well-known clinical performance characteristics documented by large registries and are used as standard of care.</i> |
| | Examples of devices falling under the category, including the risk class and classification rule used | <i>Pacing leads for right atrial or ventricular pacing (class III, rule 6), Pacing leads for pacing in the coronary sinus (class III, rule 6), Pacing leads for pacing the conduction system (class III, rule 6), Single coil defibrillation leads (class III, rule 6), Dual coil defibrillation leads (class III, rule 6)</i> |
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| 4 | Name of technology | Diagnostic and therapeutic catheters for coronary and structural interventions |
| | Short description of technology | <i>Transarterially or transvenously inserted catheters to apply contrast agent and/or coronary devices for the diagnosis and treatment of coronary artery and structural heart disease</i> |
| | Justification why WET | <i>Catheters are used for the diagnosis and treatment of coronary artery and structural heart disease for more than 40 years. There is ongoing development of existing devices and new devices. However, there are specific catheters on the market, which are used for more than 10 (up to 20) years without or only minor modification and without any safety issues. They have well-known clinical performance characteristics and are used as standard of care.</i> |
| | Examples of devices falling under the category, including the risk class and classification rule used | <i>Diagnostic coronary catheters (class III, rule 6), therapeutic guiding catheters (class III, rule 6), transseptal catheters (class III, rule 6)</i> |
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| 5 | Name of technology | Diagnostic and therapeutic intracardiac devices for coronary and structural interventions |
| | Short description of technology | <i>Transarterially or transvenously inserted intracardiac devices to perform hemodynamic measurements, intravascular imaging, coronary balloon angioplasty, specific plaque modification, stent implantation, occluder implantation for shunt occlusion, valvuloplasty, valve repair and valve implantation for the diagnosis and treatment of coronary artery and structural heart disease</i> |

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| | Justification why WET | <i>Devices are used for the diagnosis and treatment of coronary artery and structural heart disease for more than 20 years. There is ongoing development of existing devices and new devices. However, there are specific intracardiac devices on the market, which are used for more than 10 (up to 20) years without or only minor modification and without any safety issues. They have well-known clinical performance characteristics and are used as standard of care.</i> |
| | Examples of devices falling under the category, including the risk class and classification rule used | <i>(Non-steerable) diagnostic catheters and sheaths (class III, rule 6), coronary wires (Cl. III, rule 6), coronary pressure wires (Cl. III, rule 6), intravascular ultrasound catheters (Cl. III, rule 6), coronary stents (Cl. III, rule 6), valvuloplasty balloons (Cl. III, rule 6), cardiac occluders (Cl. III, rule 6), cardiac “edge-to-edge-repair” devices (Cl. III rule 6), cardiac valves (Cl. III, rule 6)</i> |