

## List of well-established technologies (WET) in Nephrology

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

	<b>Organisation:</b>	<i>German Society of Nephrology (Deutsche Gesellschaft für Nephrologie, DGfN)</i>
	<b>Contact name:</b>	
	<b>Contact email address:</b>	
<b>1</b>	<b>Name of technology</b>	<i>Haemodialysis devices</i>
	<b>Short description of technology</b>	<p><i>Included in the WET-list should be devices including the following components:</i></p> <ul style="list-style-type: none"> <li>• <i>Water treatment for the production of dialysis water, e.g., through reverse osmosis, as well as its distribution (osmosis systems, ring pipes, storage tanks), including possible devices for disinfection</i></li> <li>• <i>Production of dialysis concentrates and their possible distribution (mixing devices, liquid concentrates, cartridges)</i></li> <li>• <i>Haemodialysis machines with devices for producing the dialysis fluid, heating elements, fluid balancing, therapy monitoring, and safety features for the therapy (e.g., blood and air detection, pressure measurements)</i></li> <li>• <i>Dialyzers</i></li> <li>• <i>Tubing systems for dialysis fluid and blood, puncture needles</i></li> <li>• <i>Pre-packaged dialysis solutions with tubing systems (treatment variants)</i></li> <li>• <i>Dosing pumps for anticoagulants</i></li> <li>• <i>Consumables such as syringes, needles, infusion sets</i></li> <li>• <i>Large-bore catheters as vascular access for acute or chronic dialysis</i></li> <li>• <i>Devices for performing blood gas analyses, ECG monitors, blood pressure measurement devices, defibrillators, personal scales</i></li> <li>• <i>Dialysis beds or treatment chairs</i></li> <li>• <i>Alarm systems, staff call systems</i></li> </ul>

	Justification why WET	<p><i>The named components for haemodialysis meet the criteria listed in MDCG 2020-6<sup>1</sup> for being</i></p> <ul style="list-style-type: none"> <li>- <i>well established design, easy to use – simple and stable</i></li> <li>- <i>several decades of well-known safety</i></li> <li>- <i>well-known clinical performance characteristics &amp; standard of care with several decades of experience</i></li> <li>- <i>long history on the market</i></li> </ul>
	Examples of devices falling under the category, including the risk class and classification rule used	<ul style="list-style-type: none"> <li>• <i>FMC GENIUS®90 Akut-Therapiesystem</i></li> <li>• <i>FMC 6008 CAREsystem</i></li> <li>• <i>FMC 4008S classix</i></li> <li>• <i>FMC Akutdialyse multiFiltratePro</i></li> <li>• <i>FMC Hämodialysegerät 5008 S Standard</i></li> <li>• <i>Dialysatoren FMC FX-60, FX-80, FX-100, FX-classix-60, FX-classix-80, FX-classix-100</i></li> <li>• <i>Baxter Artis Physio Plus Multi-Therapiesystem</i></li> <li>• <i>Baxter AK 98 System</i></li> <li>• <i>Gambro AK 200 S Dialysegerät</i></li> <li>• <i>Gambro Dialysatoren Evodial Serie</i></li> <li>• <i>Gambro Prismaflex akut Dialysegerät</i></li> <li>• <i>Theranova Dialysatorserie</i></li> <li>• <i>Polyflux L-Dialysatorserie</i></li> <li>• <i>Revaclear Dialysator</i></li> <li>• <i>SWS - 5000 Series</i></li> <li>• <i>SWS-6000 Series Hemodialysis Machine</i></li> <li>• <i>DIADVANCE</i></li> <li>• <i>DIANOVA</i></li> <li>• <i>BLT Biolight</i></li> <li>• <i>NIPRO Surdial</i></li> <li>• <i>Nipro Elisio Dialysatoren 13-H, 15-H, 17-H, 19-H, 21-H</i></li> <li>• <i>BBraun Hämodialysegerät Dialog IQ</i></li> <li>• <i>BBraun Hämodialysegerät Dialog Plus</i></li> <li>• <i>BBraun Dialysatoren Diacap HiPES, LoPES</i></li> <li>• <i>BBraun Dialysatoren PES 14 - PES 22H</i></li> <li>• <i>Serumwerke Dialysatoren VitaPES-P 18HF -22HF</i></li> <li>• <i>Nikkiso Hämodialysegerät DBB EXA</i></li> <li>• <i>Nikkiso Hämodialysegerät DBB 005</i></li> <li>• <i>Nikkiso Hämodialysegerät DBB 007</i></li> <li>• <i>Akutdialyse Plasauto Sigma Citratplus mit Citrat-Option</i></li> <li>• <i>Umkehrosmose AQUAbase 500 HT</i></li> <li>• <i>Umkehrosmose AQUAbase 750 HT</i></li> <li>• <i>Umkehrosmose Aquaboss RO Dia I and II Serie</i></li> <li>• <i>Heißrein. Aquaboss Hot Rinse Smart 20</i></li> <li>• <i>Umkehrosmosen modula Serie</i></li> <li>• <i>Umkehrosmosen CentRo Serie</i></li> <li>• <i>Heißreinigung nephro SAFE</i></li> </ul>

<sup>1</sup> [https://health.ec.europa.eu/system/files/2020-09/md\\_mdcg\\_2020\\_6\\_guidance\\_sufficient\\_clinical\\_evidence\\_en\\_0.pdf](https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2020_6_guidance_sufficient_clinical_evidence_en_0.pdf)

		<ul style="list-style-type: none"> <li>• <i>Heißreinigung HDS</i></li> <li>• <i>Umkehrosmose AquaA 1800H</i></li> <li>• <i>Umkehrosmose AquaA 2700H</i></li> <li>• <i>Umkehrosmose AquaA 3600H</i></li> <li>• <i>Heißreinigung AquaHT</i></li> <li>• <i>Konzentratversorgung CCS PII Serie</i></li> <li>• <i>Konzentratversorgung CeCon Serie</i></li> <li>• <i>Konzentratversorgung CKmed</i></li> <li>• <i>Kleinosmose AquaC UNO H Serie</i></li> <li>• <i>Enthärtungsanlage Duplex Paraflow</i></li> <li>• <i>Kleinosmose HemoRO 4 ONE Heimdialyse</i></li> </ul>
<b>2</b>	Name of technology	<i>Peritoneal Dialysis</i>
	Short description of technology	<p><i>Included in the WET-list should be devices including the following components:</i></p> <ul style="list-style-type: none"> <li>• <i>Pre-packaged dialysis solutions with tubing systems</i></li> <li>• <i>Heating plates / heating systems</i></li> <li>• <i>Scales for materials and individuals</i></li> <li>• <i>Peritoneal dialysis catheters</i></li> <li>• <i>Devices for performing automated peritoneal dialysis</i></li> </ul>
	Justification why WET	<p><i>The named components for Peritoneal Dialysis meet the criteria listed in MDCG 2020-6<sup>1</sup> for being</i></p> <ul style="list-style-type: none"> <li>- <i>well established design, easy to use – simple and stable</i></li> <li>- <i>several decades of well-known safety</i></li> <li>- <i>well-known clinical performance characteristics &amp; standard of care with several decades of experience</i></li> <li>- <i>long history on the market</i></li> </ul>
	Examples of devices falling under the category, including the risk class and classification rule used	<ul style="list-style-type: none"> <li>• <i>stay•safe System</i></li> <li>• <i>sleep•safe harmony</i></li> <li>• <i>Mitra APD m.Cycler</i></li> <li>• <i>Baxter Amia Automated system</i></li> <li>• <i>Baxter HOMECHOICE</i></li> <li>• <i>Baxter HOMECHOICE PRO</i></li> <li>• <i>Baxter Homechoice Claria System</i></li> </ul>
<b>3</b>	Name of technology	<i>Apheresis</i>
	Short description of technology	<p><i>Included in the WET-list should be devices including the following components:</i></p> <ul style="list-style-type: none"> <li>• <i>Pre-packaged infusion solutions with tubing systems</i></li> <li>• <i>Apheresis devices with heating elements, fluid balancing, therapy monitoring, and safety features for the therapy (e.g., blood and air detection, pressure measurements)</i></li> <li>• <i>Apheresis filters</i></li> <li>• <i>Tubing systems for liquids and blood, puncture needles</i></li> </ul>

		<ul style="list-style-type: none"> <li>• <i>Dosing pumps for anticoagulants</i></li> <li>• <i>Technical variants are possible, in which permeate from reverse osmosis systems and downstream manufacturing units can also be used.</i></li> </ul>
	Justification why WET	<p><i>The named components for Apheresis meet the criteria listed in MDCG 2020-6<sup>1</sup> for being</i></p> <ul style="list-style-type: none"> <li>- <i>well established design, easy to use – simple and stable</i></li> <li>- <i>several decades of well-known safety</i></li> <li>- <i>well-known clinical performance characteristics &amp; standard of care with several decades of experience</i></li> <li>- <i>long history on the market</i></li> </ul>
	Examples of devices falling under the category, including the risk class and classification rule used	<ul style="list-style-type: none"> <li>• <i>Pure Metisa</i></li> <li>• <i>AFERsmart</i></li> <li>• <i>AFERsmart plus</i></li> <li>• <i>Apheresesystem Octo Nova</i></li> <li>• <i>Apheresesystem Plasauto SIGMA</i></li> <li>• <i>Delcon Giotto MONZA</i></li> <li>• <i>Mitra Blutkomponenten-Extraktor / Tisch m.Compo</i></li> <li>• <i>Apheresesystem für Transfusionen Trima Accel</i></li> <li>• <i>Plasmapheresesystem NexSys PCS</i></li> <li>• <i>Apheresesystem auf Wagen DX-21</i></li> <li>• <i>Plasmapheresesystem NexSys PCS</i></li> <li>• <i>Blutkomponenten-Extraktor / Tisch G5 Plus</i></li> <li>• <i>Therapeutisches Apheresesystem MAGELLAN</i></li> <li>• <i>Automatischer Blutkomponenten-Extraktor BIO45 (A)</i></li> <li>• <i>Therapeutisches Apheresesystem ADAorb</i></li> <li>• <i>Automatischer Blutkomponenten-Extraktor HemoPress</i></li> <li>• <i>Automatischer Blutkomponenten-Extraktor TWiN6920</i></li> <li>• <i>Automatischer Blutkomponenten-Extraktor AK - B13A</i></li> <li>• <i>Therapeutisches Apheresesystem PCM</i></li> <li>• <i>Plasmapheresesystem XJ-II</i></li> </ul>