**MDCG 2025-1**

 **EMDN Ad hoc procedure form**

 **January 2025**

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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 it is chaired by a representative of the European Commission.

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|  **Form for the submission of proposals under the ad-hoc update procedure**  | Date: |

All fields in the form are mandatory except for field 13. Requests should be submitted to SANTE-EMDN@ec.europa.eu

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| 1 | Name of NCA1 / NB 2  |  |
| 2 | Indication if the request is needed for the registration in the UDI-DI module of EUDAMED |  |
| 3 | Established need demonstration, justification as to why the request should be assessed under the ad-hoc procedure |  |
| 4 | Justification as to why currently existing codes cannot be utilised |  |
| 5 | Manufacturer’s name and authorised representative (where applicable)  |  |
| 6 | Device name or technology name under question  |  |
| 7 | Detailed description of the device or technology under question, including its intended purpose;  |  |
| 8 | Indication if this is considered a novel device 3 |  |
| 9 | Indication if the device has or will undergo an expert panel assessment |  |
| 10 | EMDN Category, Group, and Type where the code could be added |  |
| 11 | Draft term description for the new code |  |
| 12 | Reference to other devices on the market with similar technology, potentially also requiring the use of this new code (where applicable) |  |
| 13 | Additional information (e.g. reference to other nomenclature, if any) |  |