MDCG 2025-1

EMDN Ad hoc procedure form

January 2025

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

1	Name of NCA[1] / 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)	