

dHealth Intelligence Personal Health Agent

Intended purpose and classification rationale under MDCG 2019-11 Rev. 1 (June 2025)

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1. Intended purpose

The Personal Health Agent is an application for health education and communication. It supports patients in the weeks after a consultation, a diagnosis, or discharge from hospital. It explains the condition and the treatment plan in plain language, answers clarifying questions, reminds the patient of appointments, prepares the next doctor's visit, and keeps a journal whose entries the patient confirms one by one before they are saved. The Care Partner Agent serves the same purpose for family members and caregivers. The interaction follows the patient guidance of the American Medical Association on the use of AI chatbots (AI Chatbots for Health, 2026): learn, simplify, prepare for care.

The treating healthcare professional configures the agent in the HCP Console for a single course of treatment. They describe the course, choose the agent's tasks, language, and duration, and set the escalation contact for urgent concerns. This configuration is part of their professional practice within an existing treatment relationship. It is not the manufacture of a product. The generated system prompt is cryptographically attested and cannot be changed afterwards. Programs that a sponsor defines for an indication and a cohort are covered in section 5.

2. Exclusions

The intended purpose expressly excludes:

- diagnosis, differential diagnosis, or interpretation of findings beyond plain language explanation
- individual risk calculation, scores, or severity grading by the system
- treatment recommendations, or changes to medication or dosage
- capture or processing of sensor and measurement data, and monitoring of physiological parameters
- emergency care; in an emergency the agent refers to the emergency number 144, and outside Switzerland to the emergency number valid there
- automatic notification of the practice or of third parties

3. Qualification under MDCG 2019-11 Rev. 1

The guidance assesses qualification in five steps (Figure 1). The agent is software (step 1). It is neither a product listed in Annex XVI MDR nor an accessory, and it does not drive or influence a medical device (step 2). It performs actions on data that go beyond storage, communication, and simple search (step 3), and it serves the benefit of individual persons (step 4). Step 5 is decisive: the manufacturer's intended purpose must fall under Article 2(1) MDR, that is, diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease.

The intended purpose set out in section 1 is education and communication. Under section 3.1 of the guidance, software must have a medical purpose of its own to qualify as medical device software (MDSW). Software that processes or creates medical information qualifies only if that processing serves a medical purpose. On this basis the agent is not MDSW. Classification under Rule 11 of Annex VIII MDR does not apply.

Under Article 2(12) MDR, the intended purpose follows from all information supplied by the manufacturer, including promotional and sales materials. Rev. 1 stresses that an unclear intended purpose leads to misclassification. Sponsor, investor, and partner documents and the website must therefore be consistent with sections 1 and 2. A promotional claim such as “detects deterioration early” would put the classification in question, regardless of the technical implementation.

Consequence for the EU AI Act: as the agent does not qualify as a device, Article 6(1) in conjunction with Annex I does not apply. No use case under Annex III applies. In particular, the agent is not an emergency healthcare patient triage system under Annex III, point 5(d). What remains are the transparency obligations under Article 50 and the obligation under Article 4 to take measures that support AI literacy. The obligations under Article 50(1) and Article 4 are met. The AI notice and the label as an application for health education and communication are permanently visible in the agent window.

Open point. It remains to be clarified how the obligation under Article 50(2) to mark generated content in a machine-readable format applies to the agent's text output. The Commission guidelines on Article 50 of 20 July 2026 and the Code of Practice on Transparency of AI-Generated Content are decisive. For systems placed on the EU market before 2 August 2026, a transitional period runs until 2 December 2026.

4. Escalation function

The agent contains a warning sign function that cannot be switched off and sits on a locked safety floor. It is the function closest to the product boundary.

Source of the criteria. The warning signs and the matching instructions come from the healthcare professional's treatment plan or from the locked base set of generally recognised warning signs. The agent does not create criteria of its own. Functionally, displaying them is equivalent to a written action plan or a discharge instruction. The healthcare professional is responsible for criteria taken from the treatment plan, and the manufacturer for the base set. The base set is limited to generally recognised warning signs as found in public patient information, and its sources are to be documented.

No assessment of its own. The agent determines that a description meets a predefined criterion and displays the predefined instruction, for example to contact the practice or to call 144. It calculates no score, applies no weighting, grades no severity, and does not prioritise between patients.

The decision stays with the patient. An escalation triggers no automatic notification. The event is recorded in the journal if the patient confirms the entry. The decision to act remains with the patient.

This rationale is a self-assessment. The boundary is narrow: software that assesses symptom reports and derives recommendations for action on its own can qualify as a medical device under MDCG 2019-11. Under section 3.1 of the guidance, language-based matching does not count as simple search when it serves a medical purpose. The present classification therefore holds only as long as the agent reproduces predefined criteria for which a professional is responsible and contains no assessment logic of its own. No authority has confirmed it.

5. Role of the healthcare professional and distinction from manufacturing

Personalisation by the healthcare professional takes place solely within the intended purpose set out in section 1. The HCP Console allows no configuration that exceeds this intended purpose, and the safety floor cannot be switched off. The healthcare professional therefore gives the system no new intended purpose and does not make a product available under their own name. They become neither a manufacturer under Article 2(30) and Article 16 MDR nor a provider under Article 25 of the EU AI Act. Their activity remains professional practice within an existing treatment relationship. This distinguishes the configured agent from the systematic sharing of freely written prompts for language models without a medical intended purpose. There, the healthcare professional sets the intended purpose and may move into the role of manufacturer or provider.

Sponsor programs. Where a sponsor, such as a pharmaceutical company, an insurer, or a patient organisation, defines a program for an indication and a cohort, the argument of professional practice does not apply. The classification then rests on the manufacturer's unchanged intended purpose and on the limits of the console. The sponsor chooses indication, language, and duration, not the purpose. Material that the manufacturer supplies to the sponsor or approves forms part of the manufacturer's information under Article 2(12) MDR. A sponsor that offers the agent under its own name with a medical purpose claim may itself move into the manufacturer role.

6. Limits of the classification

Each of the following functions would trigger a reassessment and would probably lead to qualification as MDSW, at least Class IIa under Rule 11: severity grading or triage by the model, processing of measurement or sensor data, automatic alerting of the practice, and recommendations to adjust medication. As MDSW of Class IIa or higher, the agent would also be a high-risk AI system under Article 6(1) of the EU AI Act. Such functions will not be introduced without a prior conformity assessment.

Specialties. Section 3.2 of the guidance, extended with examples in Rev. 1, shows where the boundary lies in individual specialties. The following, among others, qualify as MDSW:

- software that lets patients with schizophrenia track symptoms and offers personalised interventions based on them
- software that tracks mood and symptoms in depression and selects exercises individually on that basis
- software that recommends personalised rehabilitation exercises from patient data for a musculoskeletal condition
- software intended to alleviate eating disorder behaviour through personalised psychoeducational exercises

For agents in physiotherapy, nutrition counselling, and mental health, the rule is therefore: the agent explains and supports what the healthcare professional has prescribed. It does not itself select exercises or interventions to treat or alleviate a condition.

Extensions. Under section 8 of the guidance, a new function can turn software into MDSW, and an added module can qualify as MDSW on its own. Every extension is therefore checked against this intended purpose before it is introduced, and the result is documented.

7. Legal framework in Switzerland and the EU

In Switzerland, the Medical Devices Ordinance (MedDO) applies. It adopts the MDR definition of a medical device. For the qualification of software, Swissmedic points to the MDCG guidance documents (information sheet on medical device software, BW630_30_007, version 3.0, April 2026). The rationale applies accordingly. Switzerland has no law specific to AI. The Federal Council intends to ratify the Council of Europe Framework Convention on Artificial Intelligence and has announced a consultation draft by the end of 2026.

The EU AI Act does not apply directly in Switzerland. It does, however, cover providers established in Switzerland that place an AI system on the EU market or whose system output is used in the EU (Article 2(1)). Article 4 has applied since 2 February 2025, and in the version amended by Regulation (EU) 2026/1744 (Digital Omnibus on AI) since 27 July 2026. Article 50 has applied since 2 August 2026. The high-risk obligations do not apply to this agent. Regulation (EU) 2026/1744 postponed them to 2 December 2027 for Annex III and to 2 August 2028 for Annex I.

This document is the manufacturer's self-assessment. No authority has confirmed it, and it does not replace legal advice in an individual case. An external legal review is recommended before it is shared with sponsors.