EFFECTUM MEDICAL
YOUR START-UP TO MARKET

Tuesday, April 09, 2024

To Whom it May Concern,

Everyman: Assessment of Applicability of Regulation (EU) 2017/745

1. Product Description

Everyman is a platform that specialises in men's health and connects patients with Swiss medical doctors and a Swiss online pharmacy. The medical professionals issue prescriptions based on a questionnaire filled in by the customer as well as an (asynchronous) chat-based conversation. If a prescription is issued, the prescription is made digitally available to the connected online pharmacy which will then fulfil the prescription and mail the medication to the patient's home.

Customer journey:

- Customers initiate a session by starting an indication-specific questionnaire.
- The questionnaire has the following purposes:
    - Identify customers that do not fall within the target group (i.e. those eligible for the use of the online platform).
    - Inform customers who do not fall within the target group that they may not use the platform.
    - Facilitate account creation for those customers who fall within the target group.
    - If they fall within the target group, collect information on the customers' preferred treatment.
- Customers with a questionnaire score that exceeds a certain pre-defined threshold are informed that they cannot use the platform:
  Leider können wir Dir die Nutzung unseres Dienstes zum jetzigen Zeitpunkt nicht anbieten. Aber wir feiern Deinen Mut, Deine Gesundheit selbst in die Hand zu nehmen! Hier sind weitere Ideen, wie Du Dein Sexleben verbessern kannst:
    - *Digitale Lösungen (z.B. für Beckenboden-Training)*
    - *Nicht-medikamentöse Lösungen (z.B. Pumpen oder Ringe)*
    - *Sexualberatung für Männer und für Paare*

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- Customers with a questionnaire score below the threshold need to answer additional questionnaire questions (multiple choice).
- The customer is prompted to create an account in order to link his responses to his person. The account is secured with his email address and a password.
- Once the account has been set up, the customer can continue completing the questionnaire. All questions as answered by the customer are visible to the treating medical professional. The answers are displayed 1:1 and are not subject to any calculations or analyses.
- At the end, the customer is lead to the check-out.
- At the checkout, the customer pays a fee for the medical service as well as makes a payment reservation for the preferred treatment (serves just as an indication for the medical professional stays independent and is free in prescribing whatever he or she deems optimal for the patient).
- After the customer has completed the check-out, the (first)-time customer is asked to verify his identity by uploading a copy of his passport.
- Based on the information provided by the customer and a text-based exchange of customer and medical professional, the medical professional can determine whether the customer is suffering from erectile dysfunction, define the treatment and issue a prescription.

4. Applicability of Regulation (EU) 2017/745 (MDR)

According to Article 2(1) of Regulation (EU) 2017/745 (European Union Medical Device Regulation – MDR), a medical device is an “instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

> — diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
>
> — diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
>
> — investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
>
> — providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

— devices for the control or support of conception;

— products specifically intended for the cleaning, disinfection or sterilization of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point."

The Everyman platform is intended to be used as a tool to facilitate remote diagnosis and treatment of a disease, namely erectile dysfunction, and may therefore be considered as having a medical purpose according to the definition of a medical device in Article 2(1) or Regulation (EU) 2017/745. As a consequence, it could potentially fall within the scope of the regulation.

Since the product is a software, the decision tree included in the guidance document *MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR* was consulted to confirm qualification as a medical device:

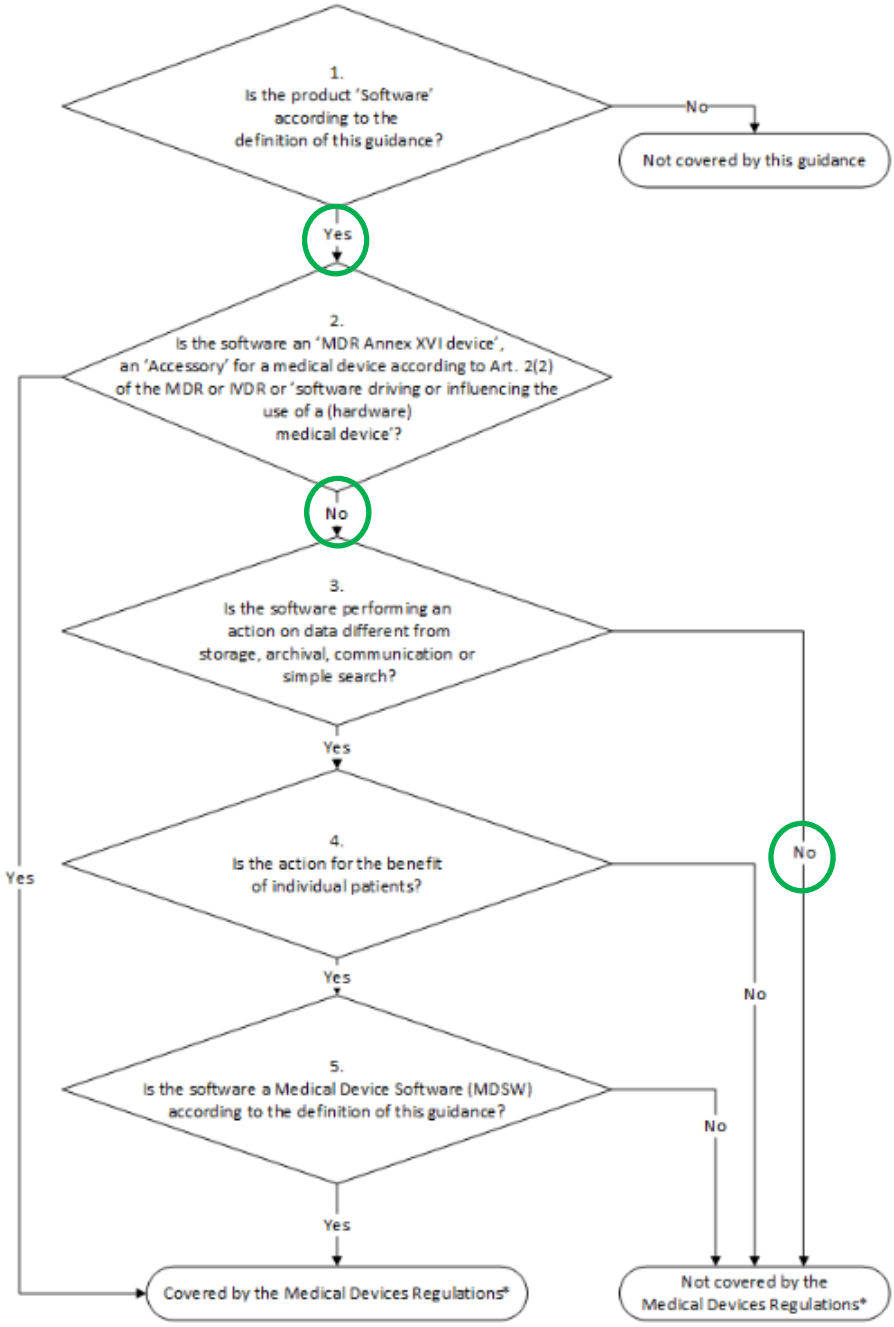

Figure 1 – Decision steps to assist qualification of MDSW

Question 1: Yes, the product is considered a software according to the definition of the guidance as it is a set of instructions that processes input data, i.e. questionnaire responses, and creates output data, i.e. information to the user regarding use of the platform.

Question 2: No, the software is neither an MDR Annex XVI device, nor is it an accessory in the meaning of the regulations or a software driving or influencing the use of a (hardware) medical device.

Question 3:

No with regard to the first part of the questionnaire: The software is adding up scores associated with questionnaire responses to an overall questionnaire score. According to the current *Manual on borderline and classification for medical devices under Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices* (version 2), simple calculations that "could be done with a basic electronic calculator or even on paper" (p. 13) are considered simple search. Addition of scores can be done manually and is therefore considered simple search.

No with regard to the second part of the questionnaire and any other downstream functionalities: The second part of the questionnaire includes multiple choice type questions only (no calculations or analyses). The medical professionals base their assessment on the information as input by the customers. Any subsequent exchanges between the medical professional and the customer do not involve actions on data different from storage, archival and communication either. Any diagnostic and treatment decisions are made based on information that is communicated through the software between medical professional and customer. The software is merely used for communication purposes and does not perform any actions on data different from communication, archival, storage and simple search.

Question 4: n/a

Question 5: n/a

Therefore, the Everyman platform is **not** considered a medical device according to Regulation (EU) 2017/745 and, consequently, does **not** fall within the scope of that regulation.

This assessment was carried out by:

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Place, date	Place, date

Sincerely,
Effectum Medical AG