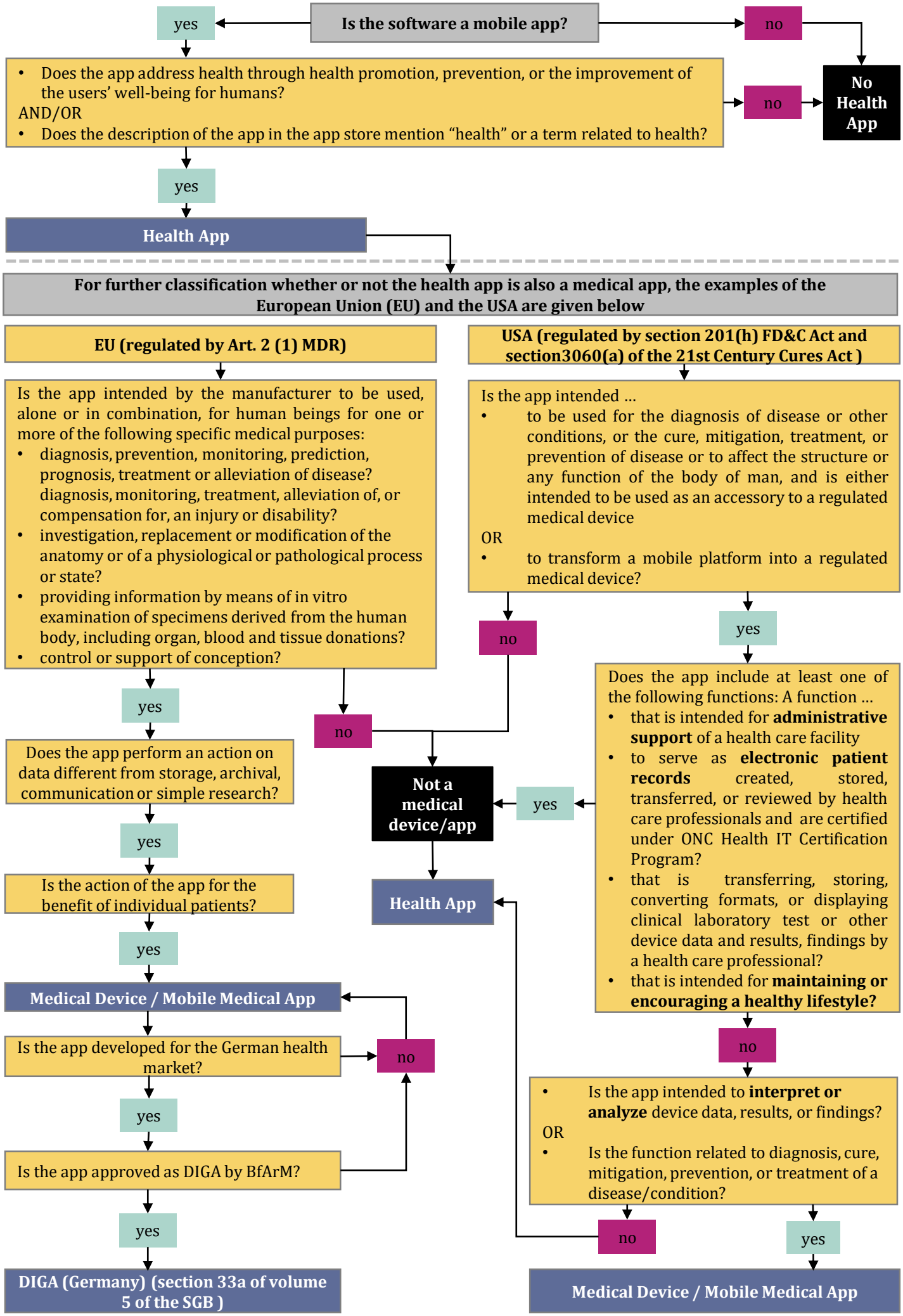
Is the software a mobile app?
yes
no
Does the app address health through health promotion, prevention, or the improvement of the users' well-being for humans?
AND/OR
Does the description of the app in the app store mention "health" or a term related to health?
no
No Health App
yes
Health App
For further classification whether or not the health app is also a medical app, the examples of the European Union (EU) and the USA are given below
EU (regulated by Art. 2 (1) MDR)
Is the app 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?
control or support of conception?
yes
no
Does the app perform an action on data different from storage, archival, communication or simple research?
yes
Is the action of the app for the benefit of individual patients?
yes
Medical Device / Mobile Medical App
Is the app developed for the German health market?
no
yes
Is the app approved as DIGA by BfArM?
yes
DIGA (Germany) (section 33a of volume 5 of the SGB)
USA (regulated by section 201(h) FD&C Act and section3060(a) of the 21st Century Cures Act)
Is the app intended ...
to be used for the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the body of man, and is either intended to be used as an accessory to a regulated medical device
OR
to transform a mobile platform into a regulated medical device?
no
yes
Does the app include at least one of the following functions: A function ...
that is intended for administrative support of a health care facility
to serve as electronic patient records created, stored, transferred, or reviewed by health care professionals and are certified under ONC Health IT Certification Program?
that is transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional?
that is intended for maintaining or encouraging a healthy lifestyle?
yes
Not a medical device/app
Health App
no
Is the app intended to interpret or analyze device data, results, or findings?
OR
Is the function related to diagnosis, cure, mitigation, prevention, or treatment of a disease/condition?
no
yes
Medical Device / Mobile Medical App