

## Template for comments and secretariat observations

Date: 16 April 2021	Document: <b>ISO/TC 215 N 3535</b> <b>ISO/DTS 82304-2</b>	Project: ISO/PRF TS 82304-2 - Health and wellness apps – quality and reliability
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MB/NC <sup>1</sup>	Line number (e.g. 17)	Clause/ Subclause (e.g. 3.1)	Paragraph/ Figure/ Table/ (e.g. Table 1)	Type of comment <sup>2</sup>	Comments	Proposed change	Observations of the secretariat
ESG member (CPME – Standing Committee of European Doctors)		4.3 Health app quality report	2 <sup>nd</sup> paragraph	Technical	To enable informed decision making, but also to create trust on the app and be transparent, the health app quality report ' <u>must</u> ' be made public. This should be a mandatory requirement, not voluntary.	<i>"The health app quality report <del>can</del> must be made available to potential customers and users of the health app to enable informed decision making."</i>	
		5.2.1.7		Technical	Amend the question criteria	<i><b>Are appropriate peer reviewed scientific literature and relevant medical guidelines used in the development of the health app?</b></i>	
		5.2	New (to add)	Technical	Add a new question criterion	<i><b>Are the app and its contents regularly updated?</b></i>	
		5.2	New (to add)	Technical	Add a new question criterion	<i><b>Can the user be reached by the app provider in case of problems (such as erroneous measurements)?</b></i>	
		5.3	New (to add)	Technical	Add a new question criterion	<i><b>Are the app's functionalities available for offline use?</b></i>	
		5.4.1.1.4	New (to add)	Technical	Add two further examples of types of information that can be provided to PII subjects.	<ul style="list-style-type: none"> <li><i><b>whether access to data on the mobile device is asked or needed.</b></i></li> <li><i><b>the period for which account data will be retained.</b></i></li> </ul>	

1 **MB** = Member body / **NC** = National Committee (enter the ISO 3166 two-letter country code, e.g. CN for China; comments from the ISO/CS editing unit are identified by \*\*)

2 **Type of comment:** **ge** = general **te** = technical **ed** = editorial