

AS IEC 82304.1:2022  
IEC 82304-1:2016



# Health software

## Part 1: General requirements for product safety



AS IEC 82304.1:2022

This Australian Standard ® was prepared by IT-014, Health Informatics. It was approved on behalf of the Council of Standards Australia on 09 July 2022.

This Standard was published on 22 July 2022.

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- Australian College of Nursing
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This Standard was issued in draft form for comment as DR AS IEC 82304.1:2022.

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First published as AS IEC 82304.1:2022.



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## Preface

This Standard was prepared by the Standards Australia Committee IT-014, Health Informatics.

The objective of this document is to provide requirements for the safety and security of health software products designed to operate on general computing platforms and intended to be placed on the market without dedicated hardware, with a primary focus on the requirements for manufacturers. It covers the entire lifecycle including design, development, validation, installation, maintenance, and disposal of health software products.

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