



BSI Standards Publication

Health software and health IT systems safety, effectiveness and security

Part 2-1: Coordination — Guidance and requirements for
the use of assurance cases for safety and security

National foreword

This Published Document is the UK implementation of ISO/TS 81001-2-1:2025.

The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its committee manager.

Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient's own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

This publication is not to be regarded as a British Standard.

© The British Standards Institution 2025
Published by BSI Standards Limited 2025

ISBN 978 0 539 17684 1

ICS 35.240.80

Compliance with a Published Document cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 January 2025.

Amendments/corrigenda issued since publication

Date	Text affected
------	---------------