

ICS 11.100.20
CCS C30



**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 16886.2-2026

Replacing GB/T 16886.2-2011

**Biological evaluation of medical devices - Part 2: Animal
welfare requirements**

医疗器械生物学评价 第2部分：动物福利要求

(English Translation)

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Foreword

GB/T 16886.2-2026 is a recommended national standard (GB/T) of the People's Republic of China, issued on 28 January 2026 by the State Administration for Market Regulation and the Standardization Administration of China, with effect from 1 February 2027.

This edition replaces GB/T 16886.2-2011.

The document adopts an international standard (ISO or IEC).

It is under the responsibility of the National Medical Products Administration.

Classification: ICS 11.100.20; CCS C30.

1 Scope

Biological safety testing of medical devices sometimes involves animals, and this standard, Part 2 of the biological evaluation series, deals with animal welfare requirements. It addresses the ethical conduct of such work and sits alongside the other parts of the series that cover the evaluation process and individual tests. It is a recommended national standard.

Medical device manufacturers, contract research and testing organisations, animal facility managers, regulatory affairs specialists and ethics committees are the principal readers. Companies preparing biocompatibility evidence for registration in China will need to know how animal use is expected to be managed.

The standard was issued on 28 January 2026 and takes effect on 1 February 2027. It replaces GB/T 16886.2-2011. Test facilities and sponsors that have built their procedures on the earlier edition should plan to review them before the new one applies.