

ICS 11.100
CCS C30



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

GB/T 16886.17-2025

Replacing GB/T 16886.17-2005

**Biological evaluation of medical devices - Part 17: Toxicological
risk assessment of medical device constituents**

医疗器械生物学评价 第17部分：医疗器械成分的毒理学风险评估

(English Translation)

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Foreword

GB/T 16886.17-2025 is a recommended national standard (GB/T) of the People's Republic of China, issued on 29 August 2025 by the State Administration for Market Regulation and the Standardization Administration of China, with effect from 1 September 2026.

This edition replaces GB/T 16886.17-2005.

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

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

Classification: ICS 11.100; CCS C30.

1 Scope

Part 17 of the biological evaluation series describes how the toxicological risk of the constituents of a medical device is assessed. According to its scope, it specifies the process and requirements for this assessment, together with the methods and criteria used to decide whether exposure to a constituent is without appreciable harm.

The assessment can form part of the biological evaluation of the finished product and applies to chemical characterization information, such as compositional data or extractables and leachables results. The scope also lists circumstances where the process is not intended to apply, for example where exposure falls below a toxicologically based reporting threshold or where equivalence to an established device has already been shown.

Manufacturers, toxicologists, biocompatibility consultants, test laboratories and regulatory affairs teams will use it when preparing evidence for registration. The standard was issued on 29 August 2025 and takes effect on 1 September 2026, replacing GB/T 16886.17-2005. It is a recommended national standard.