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Hongru Du

YY/T 1815-2022 Translated English of Chinese Standard (YY/T1815-2022, YYT 1815-2022)

<https://www.chinesestandard.net>,2022-08-21 This document specifies the method that uses threshold of toxicological concern (TTC) to assess the biocompatibility of constituents of a medical device. This document applies to: - Compare with the maximum concentration of identified or unidentified constituents in an extract (see GB/T 16886.18); - Toxicological equivalence studies; - Comparison with the estimated maximum exposure dose for an identified constituent (see GB/T 16886.17).

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