

August 14, 2026

CDSCO

Device rules add EU countries to rule 63 and QMS for Class A

G.S.R. 744(E) adds European Union countries to rule 63(1) of the Medical Devices Rules, 2017 and Quality Management System to rules 19H and 19J.

G. S.R. 744(E), DATED August 14, 2026, is a notification of the Ministry of Health and Family Welfare (Department of Health and Family Welfare) making the Medical Devices (Third Amendment) Rules, 2026. It was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No.

678, on August 19, 2026. The Central Government makes the rules under sections 12 and 33 of the Drugs and Cosmetics Act, 1940, after consultation with the Drugs Technical Advisory Board. Unless specified otherwise, they come into force on the date of their final publication in the Official Gazette.

KEY FACTS

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G.S.R. 744(E), the Medical Devices (Third Amendment) Rules, 2026



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The rules make four amendments to the Medical Devices Rules, 2017. In rule 63, sub-rule (1), proviso (iv), the words "or European Union countries" are inserted after the words "or Japan". In rule 19H, sub-rule (2), clause (v), and in rule 19J, sub-rule (2), clause (v), the words "and Quality Management System" are inserted after the word "standards". The marginal heading of rule 19 is substituted with "Government Medical Device Testing laboratories".

The notification does not restate the provisions it amends; each change is an insertion or substitution of words in the existing rules. A draft of these rules was published as G.S.R. 269(E) on April 10, 2026, inviting objections and suggestions within thirty days from the date the Gazette copies were made available to the public, which was April 10, 2026. The Central Government considered the objections and suggestions received. The notification is signed by Harsh Mangla, Jt. Secy. (F. No. X.11035/112/2024-DR).

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Rule 63(1), proviso (iv)	"or European Union countries" inserted after "or Japan"
Rules 19H(2)(v) and 19J(2)(v)	"and Quality Management System" inserted after "standards"
Rule 19 heading	"Government Medical Device Testing laboratories"
Draft	G.S.R. 269(E), April 10, 2026
Signed by	Harsh Mangla, Jt. Secy.

[The notification](#) (PDF, 740 KB)

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IndusDesk

hello@indusdesk.com · +91 98917 60000

9th Floor, Hemkunt House, Rajendra Place, New Delhi, Delhi 110008, India

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