

August 14, 2026

CDSCO

Device labels to carry sterilization site licence number

G.S.R. 743(E) requires device labels to show an outsourced sterilization site's licence number and adds a Ninth Schedule of test and evaluation fees.

G. S.R. 743(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 (Second Amendment) Rules, 2026. It was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No.

677, 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, the rules come into force on the date of their final publication in the Official Gazette.

KEY FACTS

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Ministry of Health and Family Welfare
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G.S.R. 743(E), the Medical Devices
(Second Amendment) Rules, 2026



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For labels, the rules insert a new clause (p) after clause (o) of rule 44. Where a medical device manufacturer has outsourced the sterilization activity to the site of another facility holding a valid licence to carry out the sterilization process of medical devices, the licence number of the sterilization site should be mentioned on the label of the device, preceded by the words "Sterilization sites Manufacturing License Number" or "Ster. Mfg. Lic. No." or "S.M. L.". In clause (o) of rule 44, the words "and (m)" are substituted by "(m) and (p)." Compliance with clause (p) is mandatory with effect from six months from the date of the notification.

The rules also insert a Ninth Schedule, "Fee for test or evaluation" (see rules 19 and 69), after the Eighth Schedule. It sets the cost of each test or evaluation in rupees (INR), from 150 each for tests such as absorbency, foreign matter and threads count to 5000 for an implantation test. Charges for a test or evaluation not specified in the table are to be determined by the Director or Medical Device Testing Officer of the laboratory or institute, as the case may be, and the prescribed cost increases automatically by 5% annually.

A new sub-rule (3) in rule 19, in Chapter III, states that the fees for test or evaluation are those specified in the Ninth Schedule. In rule 69, in Chapter IX, the words "accompanied with a fee specified in the Ninth Schedule" are inserted after the words "Form MD-33". In rule 3, the words "of a licensee" are omitted from clause (j), and a new clause (ya) defines "Certificate of Registration" as a registration certificate granted by the State Licensing Authority or the Central Licensing Authority in Form MD-2, Form MD-40 and Form MD-42, as the case may be.

A draft of these rules was published as G.S.R. 270(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). The Medical Devices Rules, 2017 were published by notification number 78(E) dated January 31, 2017 and last amended by G.S.R. 165(E) dated March 2, 2026.

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Document	G.S.R. 743(E), the Medical Devices (Second Amendment) Rules, 2026
Dated	August 14, 2026
Published	Gazette of India, Extraordinary, No. 677, August 19, 2026
Amends	Medical Devices Rules, 2017: rules 3, 19, 44 and 69, and a new Ninth Schedule
Label requirement	Licence number of the outsourced sterilization site, under clause (p) of rule 44
Label requirement mandatory	Six months from the date of the notification
Test fees	Ninth Schedule, rising automatically by 5% annually
Draft	G.S.R. 270(E), April 10, 2026
Signed by	Harsh Mangla, Jt. Secy.

Ninth Schedule: Fee for test or evaluation

Sr. No.	Type of Test/Evaluation	Cost of Test/Evaluation in rupees (INR)
1.	Implantation test	5000
2.	Sterility test	2000
3.	Surgical Dressings	1000
4.	Syringes & needles	1000
5.	Physical test / Physiochemical test for perfusion sets etc.	2000
6.	Surgical Sutures	3000
7.	Optical Rotation, Specific Gravity, Refractive Index, weight per ml, Fluorescence etc.	250 each
8.	Absorbency, Weight per unit area (Surgical), Foreign matter, Extractive value, Threads count, Length & Width (Surgical), Surface active substances, Acidity or alkalinity, Neps, Setting time etc.	150 each
9.	Condoms	2500
10.	Intrauterine Devices	2500
11. a.	Bacterial endotoxin test: Qualitative	3000

11.	Bacterial endotoxin test: Quantitative	4500
b.		

[The notification](#) (PDF, 799 KB)

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