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Class 2 Device Recall Heidelberg Engineering GmbH SPECTRALIS with Flex Module



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Class 2 Device Recall Heidelberg Engineering GmbH SPECTRALIS with Flex Module



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Date Initiated by Firm	August 06, 2026
Date Posted	September 18, 2026
Recall Status ¹	Open ³ , Classified
Recall Number	Z-3215-2026
Recall Event ID	99595 ²³
510(K)Number	K181594 ²⁴
Product Classification	Tomography, optical coherence ²⁵ - Product Code OBO ²⁶
Product	Brand Name: Heidelberg Engineering GmbH Product Name: SPECTRALIS with Flex Module Model/Catalog Number: S3610, S2610, S2000, S1610 multimodal imaging platform optimized for the posterior segment of the eye
Code Information	UDI-DI 04059237000235 Lot Code: Spec-07265, Spec-11121, Spec-11281, Spec-12096, Spec-13305, Spec-14403, Spec-15282, Spec-15587, Spec-20071, Spec-20348, Spec-20351, Spec-20591, Spec-20605, Spec-23473, Spec-23941, Spec-23950, Spec-23975, Spec-24507, Spec-24558, Spec-24582, Spec-24611
FEI Number	3002807157
Recalling Firm/ Manufacturer	Heidelberg Engineering GmbH Max-Jarecki-Str. 8 Heidelberg Germany
Manufacturer Reason for Recall	Wheels may come loose when module is being pushed or pulled during movement or transportation, affecting stability of the stand. The stand may tip over as a result. Falling stand may cause impact or crushing injuries, particularly to the feet, legs, hands or arms of the operator or nearby persons.
FDA Determined Cause ²	Component design/selection
Action	Firm began notifying US customers on August 6, 2026 via email. Instruction to Customers: There is a possibility that the castor wheels of the Flex stand are not properly attached. The wheels may come loose when the Flex Module is being pulled or pushed during movement or transportation, affecting the stability of the stand. As a result, the Flex stand may tip over if not correctly handled or supported by the operator. Users shall schedule a service appointment with your Heidelberg Engineering service partner as soon as possible so that the castor fastenings can be inspected and, if necessary, corrected.
Quantity in Commerce	87

Distribution

Worldwide - US Nationwide distribution in the state of Massachusetts and the countries of Australia, Costa Rica, Germany, France, India, Israel, Italy, Canada, Mexico, Netherlands, Austria, Philippines, Poland, Saudi Arabia, Switzerland, Spain, South Africa, Thailand, Czech Republic, United Kingdom, Vietnam.

Total Product Life Cycle [TPLC Device Report](#)²⁷

¹ A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about [medical device recalls](#)²⁸.

² Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

³ The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database

[510\(K\)s with Product Code = OBO](#)²⁹

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