State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

California Device Recall Information Sheet

Medos International Sarl Recalls CERENOVUS CEREBASE DA Guide Sheath For Fractures At The Distal End

Recall Date	Product Description	Recalling Firm	Recall Reason
3/20/2024	**Cerenovus Cerebase Da Guide Sheath** Part Numbers: a) GS9080SD; b) GS9090SD; c) GS9095SD; Vascular guide-catheter, single-use	**Medos International Sarl** Le Locle, Switzerland	Medos has received an increase in complaints for CEREBASE DA Guide Sheath with reports of fractures at the distal end, which may result in surgical procedural delay, vascular injury and in extreme rare occasions it may result in embolism.

Recall Class	Product Identification	Distribution	Affected Dates
I	**CERENOVUS CEREBASE DA Guide Sheath** a) GS9080SD: UPDATED 4/4/2024 UDI-DI 10886704082316, Lot numbers: 31121042 to 31212661; b) GS9090SD: UPDATED 4/4/2024 UDI-DI 10886704082293, Lot numbers: 31094249 to 31225738; c) GS9095SD: UDI-DI 10886704082323, Lot Numbers: 31208992, 31212656	1343 Units Worldwide	February, 2024 and prior

For additional information, please visit the FDA website

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