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2

TECHNICAL DATA SHEET

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Effective Date
14Apr2023

SURGICAL MARKING PENS

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Product Family	Surgical Marking Pens
Intended Use	Intended for surgical marking on intact skin
Description	The Aspen Surgical Marking Pens are used to define incision site(s) preoperatively. A variety of barrel and tip options are available depending on preference as well as the inclusion of rulers and/or labels. The Marking Pens are composed of two different formulations of ink: Gentian Violet and Chloraprep® Resistant ink, respectively.
Picture of Device	
Manufacturer Name and Address	<p>Aspen Surgical Products, Inc. 6945 Southbelt Dr. SE Caledonia, MI 49316, USA</p> <p>Duns #027680821 Tax ID #38-3448946</p>



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Certifications	<p>ISO 13485 FM 703043 MDR 755274 R000 MDSAP 690516 UKCA 776646</p> <p>Available on Aspen's website: https://www.aspensurgical.com/compliance/certificates/</p>
Sterilization Information	<p>Gamma: Sterigenics 1003 Lakeside Dr. Gurnee, Illinois 60031, USA</p>
European Union Classification and Conformity Route	<p>MDD: Class I under Rule 1 per Annex IX MDR: Class I under Rule 1 per Annex VIII</p>
Authorized Representative of the European Union	<p>Emergo Europe Westervoortsedijk 60 6826 AT Arnhem The Netherlands</p>
EU Notified Body	<p>BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam</p> <p>Notified Body Number: 2797</p>
Canadian Classification and License Number (If applicable)	<p>Class I, Rule 7 Medical Device License: N/A – Product is a class 1 device in Canada and does not require a medical device license.</p>
FDA Regulatory Class and Product Code Registration #	<p>21 CFR 878.4660 Marker, Skin Medical Device Listing Number: D359004 Product Code: FZZ Product Class: Class 1 510k Submission Type: Exempt</p>
Instruction Insert (IFU)	<ol style="list-style-type: none"> 1. WriteSite Marking Pens NS IFU: 20200082 2. WriteSite Marking Pens Sterile IFU: 20200081 3. Aspen Marking Pens NS IFU: 20190068



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4. Aspen Marking Pens Sterile IFU: 20190067
5. Marking Pens and Sterile IFU 201220023
6. Marking Pens Sterile IFU: 20190070
7. Marking Pens NS IFU: 20182011
8. Aspen Ruler NS IFU: 20200056
9. Skin Markers IFU: 20210007
10. WriteSite Plus Multi Ink Marker Sterile IFU: 20210003
11. WriteSite Plus Multi Ink Marker NS IFU: 20210004

IFU's provided with product and available on Aspen's website:
<https://www.aspensurgical.com/education/instructions-for-use/>

Material Composition

Surgical Marker Pen Configuration:
 Cap, Barrel and Plug: Polypropylene, Co-Polymer Resin, Colorant
 Nib: Fine: Polyacetal, Regular: Polyester Fiber, Phenoxy Resin
 Reservoir: Polypropylene/Polyester
 Ink: Proprietary

ChloraPrep Resistant Surgical Marker Pen Configuration:
 Cap, Barrel and Plug: Polypropylene, Co-Polymer Resin, Colorant
 Nib: Polyester
 Reservoir: Polypropylene/Polyester
 Ink: Proprietary

Skin Markers contain substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR') of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council.

Neither Configuration contains reportable amounts of:

- Natural latex rubber
- Polyvinylchloride (PVC)
- Phthalates
- Bis (2-ethyhexyl) phthalate (DEHP)
- Bisphenol A (BPA)
- Potential contamination by bovine or transmissible spongiform encephalopathies (BSE/TSE).

Available on Aspen's website:
<https://www.aspensurgical.com/compliance/sds-sheets/>



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RoHS under DIRECTIVES 2011/65/EU as amended by Directives 2015/863 & 2017/2102	Not Applicable. This device does not consist of any electrical & electronic equipment
REACH Regulation 1907/2006	Gentian Violet (CAS 548-62-9) is present in the ink.
California Proposition 65	Gentian Violet (CAS 548-62-9) is present within the ink and a warning is on the product labeling.
Biological/Biocompatibility Report	<p>The following tests were performed per ANSI/AAMI/ISO 10993 and device to pose no biological risk:</p> <p>Cytotoxicity per ISO 10993-5:2009</p> <p>Dermal Sensitization per ISO 10993-10:2013</p> <p>Irritation/Intracutaneous per ISO 10993-10:2013</p> <p>Conclusion: Devices pose no biological risk.</p>
GMDN Number and EMDN number, if applicable	<p>GMDN: 61575, Surgical Marking Pens</p> <p>EMDN: V9004, Surgical Marking Pens</p>
Shelf Life	<p>Fine Tip: 2-year shelf life</p> <p>All other configurations: 5-year shelf life</p>
Country of Origin	USA and China
Tariff Codes	<p>HTS: 9608.20.0000</p> <p>HS: 9608.20.0000</p>
Radiopaque	N/A – Devices are not radiopaque