



Technical Data Sheet Marking Pens

Product:	Skin Marker – Sterile and Non-sterile Utility Marker – Sterile and Non-sterile
Intended Use	Skin Marker is used for surgical marking on intact skin. Utility marker is used for marking labels, containers, etc.
Materials	Barrel, cap and plug: polypropylene Reservoir and nib: polyester Skin Marker Ink: Gentian violet and isopropanol alcohol Utility Marker Ink: 5277 black ink and propyl alcohol MSDS for inks can be found on the company website Skin and Utility Marker are Latex-Free
Manufacturer	Aspen Surgical Products, Inc. 6945 Southbelt Drive SE Caledonia MI 49316 USA
Type of Sterilization, Name and Address of Contract Sterilizer	Type of Sterilization: Gamma Radiation Sterilizer: Sterigenics (IBA) 1003 Lakeside Drive Gurnee, IL 60031
Legal Address of Representative of the European Union	Aspen Medical Europe Ltd. Thornhill Road, North Moons Moat Redditch Worcestershire B98 9NL United Kingdom
Storage	No special storage requirements.
Canadian Rule / Classification	Skin Marker - Rule 7, Class I; Non-invasive device Utility Markers- Not considered a Medical Device
FDA Regulatory Class and Product Code	Skin Marker: 21 CFR 878.4660 Skin Marker Product Code: FZZ, Class I Utility Marker: Not a medical device
EU Classification	Skin Marker - Rule 1, Class I Non-invasive device used with intact skin Annex V, article 3 Utility Markers- Not considered a Medical Device