



The differences between Certified Medical and Consumer Grade

The following information is intended to provide a better understanding of the differences between Medical and Consumer grade CDs. Through standardization efforts in place through NEMA, ACR, ACC and the DICOM committee, CD-R has emerged as the standard for exchange media. Because of this standardization, it is very important to understand that all CD-R media is not the same and that the medical use of CD-R media requires special consideration when choosing a manufacturer. MediScribe Medical Certified Media is specifically designed to safeguard the integrity of medical images in mission critical applications.

The Federal Government recently issued new regulations for medical image management devices, which includes the media used in those devices. To ensure that you are purchasing true medical grade recording media, ask your media vendor if their products comply with the following U.S. Federal Regulations: 1) FDA Class 1; 2) Establishment Registration of manufacturing facilities; 3) Device Registration of product itself; 3) Current good manufacturing practices in accordance with guidelines set by the FDA (CGMP); 4) Employing Labeling of Medical Devices; 5) Employing Medical Device Reporting.

MediScribe has implemented superior quality control in producing the only known FDA approved Medical Certified Media line. In addition to the regulatory piece, MEDISCRIBE provides a CD-R, which is without peer in the marketplace. MediScribe's Certified Medical CD-R goes beyond traditional manufacturing specifications by adding such features as a UV filter for sunlight protection and pre-grooving of the substrate for superior error reduction in readers and writers. MediScribe's Medical CD-R substrate is of the highest purity and quality. Even a slight contamination in the CDs substrate may result in an uncorrectable error after the disc ages for only a short time. Injection molding, stamper quality and over-coating are also very critical to substrate performance. MediScribe uses a proprietary stamper and substrate for its medical CD-R, and the whole manufacturing process is performed in a state of the art cleanroom. These factors are critical in the recording process, especially for the higher speed writers.

The limits or shortcomings of other CD brands and manufacturing techniques may not be evident during the recording process. Recording a CD is not the true test, especially where the CD is used for medical image exchange. The other common flaws of CD-R media lie in their expected lifetime, and in their ability to be read by a wide array of CD readers. MediScribe uses a special reflective layer. This provides superior reflectivity and has the highest stability to resist corrosion. Corrosion can introduce errors and cause the disc to become unreadable. Another aspect of compatibility is the dye material. The dye coating must be free from defects and controlled to tight tolerances in order to have error free performance. Inferior dye formulations will cause problems in some readers and writers. MediScribe uses a proprietary dye formula to insure a 100-year life expectancy. This dye is specially tuned to work with the CD Writers and Readers most commonly used in the medical industry. Finally, as CD readers age their lasers lose power. MediScribe's medical substrate and special dye provide the required integrity to record under compromised conditions.

MediScribe Medical Grade is manufactured to tolerances far more exacting than conventional consumer grade discs. MediScribe's regulatory adherence and engineering expertise lend themselves to good patient outcome, and may close the window of liability that may exist with other brands.



Magneto Optical

MediScribe Certified Medical Magneto Optical Disks are manufactured to tighter specifications and tolerances far more exacting than standard or commercial grade MO. It is specifically designed to safeguard the integrity of medical images and mission critical applications.

MediScribe Certified Medical MO is the only known stand-alone MO which adheres to the FDA's new guidelines for medical image management devices. Our MO has to follow strict FDA guidelines: 1) Establishment Registration of manufacturing facilities; 2) Device Registration of product itself; 3) Current good manufacturing practices in accordance with guidelines set by the FDA (CGMP); 4) Employing Labeling of Medical Devices; 5) Employing Medical Device Reporting.

If the MO you are currently using is not medical grade, you may not be exposed to its shortcomings until it's too late. Some less stringent manufacturing techniques may not be evident until some time has passed. Lost or distorted images cannot be reproduced or rerecorded. No manufacturer, including MediScribe, can guarantee against any failure rate, but MediScribe Certified Medical will decrease the margin of error that can occur with other brands.

MediScribe Certified Medical may be the first step towards HIPAA compliance in your institution.

The FDA requires that you use regulated media in your regulated medical systems. This is not to say that the FDA is checking up on what type of media is being used in the medical field. What is of concern with many institutions is that MediScribe Certified Medical may help close the window of liability that may exist with other brands.

Medical Certified MO is manufactured to an acceptable error rate of less than 200 sector errors per disk. To put that into perspective, the industry standard for MO set forth by ISO 9002 is 1000 bad sectors per disk. In summary, MediScribe Certified Medical is at least 80% better than the acceptable industry standard.

Most of the archiving software sets parameters of acceptable error rates at 400 to 600 per disk. If this level is exceeded, the program will reject the disk. Rejection may occur before any writing to the disc has been done during the formatting process which checks for errors before writing begins. If this error level is reached after recording has begun, it is most likely due to an error in the software or fluctuations in laser strength during recording. With MediScribe Certified Medical the error rate is greatly reduced and allows a wider margin of error during the recording process to reduce the amount of failed discs, resulting in less tech time, frustration and most importantly corrupt medical images.