MGRM's strong focus on processes and standards has ensured that we comply with all known global standards.

In the United States, our products are approved by the US Food and Drug Administration; in Europe our products are CE certified while in Russia our products have passed Toxicological and Clinical Trials. Our internal processes are being adhered to ISO 9001 and ISO 13485 certified. We also have World Health Organization's Good Manufacturing Practice (GMP), Environmental Management Systems ISO 14001 as well as Occupational Health and Safety OHSAS 18001:2007 accreditations.

All our products are manufactured using advanced methods and machinery and, more importantly, through advanced manufacturing processes. A world-renowned leader for process-quality accreditation, DNV of Norway, has audited our processes during 2005 - 2008 and now, by Moody International of UK. MGRM Medicare is perhaps one the few companies in the area of rehabilitation that has its products and processes evaluated by the world quality organizations and obtained all certifications relevant for the industry.

US-FDA & CE (Clinical Approvals)
MGRM Splints undergo extensive clinical tests.

MGRM has the **United States – Food and Drug Administration** registration required for marketing products in the United States.

MGRM also has the **Certificate of Conformity (CE Marking)** required for marketing in European Union countries.
MGRM has cleared toxicological and clinical trials in many of countries in Asia, Middle East and other continents.

ISO 9001: 2008 / ISO 13485:2003 – Quality Standards
ISO 9001 is awarded to MGRM for its **"quality management"**. This certification endorses that MGRM fulfills the following important norms -

- **Customer's** quality **requirements**
- Applicable **regulatory requirements,** while aiming to
- Enhance **customer satisfaction,** and
- Achieving **continual improvement** of its performance in pursuit of these objectives.

ISO 13485:2003
ISO 13485:2003 is awarded for its specific compliance with respect to **MGRM medical devices** that meet

- **Customer's** quality **requirements**

- Applicable **regulatory requirements**

ISO 14001:2004 - Environmental Management System Standards
The **ISO 14001** is awarded to MGRM for its **"environmental management"**. This certificate endorses that MGRM:

- **Minimizes harmful effects** on the environment and
- Achieves continual improvement of its environmental performance

OHSAS 18001: 2007 - Occupational Health and Safety Management System
MGRM is awarded OHSAS 18001: 2007 indicating that all risks pertaining to occupational health and safety at MGRM Manufacturing sites have been taken care, and have been eliminated or minimized. It indicates that MGRM is also aware of such risks and regularly audits and eliminates them as and when the issues arise.

WHO GMP - Good Manufacturing Practices
World Health Organizations Good Manufacturing Practices (GMP) is a system that ensures that MGRM Products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in production that cannot be eliminated through testing the final product.

The main risks are:

- Unexpected contamination of products, causing damage to health or even death
- Incorrect labels on containers, which could mean that patients receive the wrong product

- Insufficient design resulting in ineffective treatment or adverse effects.

GMP covers all aspects of MGRM production, from raw materials, premises and equipment to training and personal hygiene of staff. Detailed, written procedures are available for each process that could affect the quality of the finished product.

MGRM system provides documented proof that correct procedures are consistently followed at each step in the manufacturing process - every time a product is made. WHO has established detailed guidelines for good manufacturing practice with which MGRM complies.

MGRM Medicare’s recognition and certifications

- FDA (United states Food & Drug Administration) approval
- Certificate of Conformity (CE Marking) for Europe
- Good Manufacturing Practices (GMP) certified by WHO
- ISO 9001: 2008
- ISO 13485:2003
- ISO 14001:2004 (for Environmental Management Systems)

- OHSAS 18001: 2007

ANVISA

The National Health Surveillance Agency (AgênciaNacional de VigilânciaSanitária – ANVISA) is responsible for the registration of medical devices in Brazil and assigns a unique 11-digit identification number to each device, according to specific resolutions. Many of the products from MGRM's bandage to splintage™ line are registered with ANVISA.