

GS1 Healthcare - Small Medical Instrument Marking

Date: 03-February-2009

CR #: 09-000026

This is a GSMP **Call-to-Action** to recruit users from all industries and from everywhere in the world to bring their expertise, commitment, and contribution to a new GSMP work area.

The information herein gives a general description of the new work area and the **GS1 Healthcare Small Instrument Marking Work Group (WG)** that is being formed to accomplish the work. For information on how to join this work area, please refer to Section 12 below.

1. Objective/Scope of the GS1 Healthcare Small Instrument Marking Work Group

- The current standards accommodate marking of a high percentage of existing medical instruments. This group is being formed to standardize the marking for those instruments too small to be covered by the existing standards.
- The group will create a Business Requirements Analysis Document (BRAD) to record the global business requirements for direct marking of healthcare specific small medical / surgical instruments in the global healthcare supply chain. The marking is for automatic identification and data capture (AIDC) with the specific focus on patient safety and instrument tracking. For this Call To Action the supply chain starts at the manufacturer with the finished instrument and ends at the point of patient care with the added aspect of instrument processing and reuse. Healthcare products within the scope of work are: Medical / Surgical Instruments. The AIDC carrier is GS1 DataMatrix. The GS1 Healthcare AIDC Application Standards Work Team has gathered as part of their Phase 1 work the global business, data and carrier requirements for small medical / surgical instrument marking. All this information will be made available to and used by this group.
- The group will create a GS1 General Specification Change Notice (GSCN) for the enhancement of the GS1 General Specification. The GSCN is the approved document to be developed, approved and ratified. GSCN's are the recognized standard until incorporated into the GS1 General Specification during the annual publication cycle. The GS1 Healthcare AIDC Application Standard for Small Instrument Marking which will highlight the changes to the appropriate sections of the GS1 General Specification will become attached to the covering GSCN form.

2. Scope Constraints of the GS1 Healthcare Small Instrument Marking Work Group

GSMP WGs and BRGs must adhere to the GS1 Standards Development Methodologies to assure their scope and deliverables, upon which the work of the other GSMP groups depends.

Generally, the team must operate within the following context:

- Develop documents that capture the business and technical requirements
- Develop documents that capture the additional considerations and concerns that were discussed during the group's calls and physical meetings.

This work effort is based off of Change Request: **#09-000026**.

3. Expertise Required

This is a call for AIDC, Healthcare (all stakeholders including manufacturers, hospitals, sterilization centers, etc.), business information, and business information technology experts for the **GS1 Healthcare Small Instrument Marking Work Group**. The experts should represent trading partners from both sides of the trading relationship, third parties, and solution providers to have proper representation on the WG/BRG. The intent is to have balanced membership from the **GS1 Global Healthcare Sector** user community to define and establish proper global standards with the clear intention of implementation of these.

The **GS1 Healthcare Small Instrument Marking Group** will also, where appropriate, consult with and seek advice from the experts in the Bar Codes and Identification Technology Group to ensure that the solutions are technically and economically feasible.

3.1. Sector-Specific Expertise Required

This section is for sector specific Calls-To-Action.

Sector leadership has determined the following areas of expertise may participate in requirements gathering, solution development, and eBallot.

Please indicate either **Yes** or **No** for all that apply:

Expertise	Requirements Gathering	Solution Development	eBallot
GS1 Member Organizations (MO)	Yes	Yes	Yes
Suppliers / Manufacturers	Yes	Yes	Yes
Retailers	Yes	No	Yes
Data Pools	No	No	No
Hospitals	Yes	Yes	Yes
Regulatory Agencies	Yes	Yes	Yes
Associations	Yes	Yes	TBC
Wholesalers / Out-Sourcers	Yes	Yes	Yes
Medical Professionals (Doctors, Hospital Staff, etc.).	Yes	Yes	Yes
Solutions Providers	No	As needed at the discretion of the Project Leaders	No

Note: Public review is open to all Community Room Participants



4. Area's Affected

The task of this work group will affect the GS1 General Specifications Publication Team as the output from this work group will become an input to their annual GS1 General Specification publication activities. The Healthcare Application Standard for Small Instrument Marking will be an attachment to the General Specification Change Notice (GSCN).

This work group will maintain a liaison with other GS1 Healthcare work groups to assure harmonization among work products.

This work group will collaborate with the Local Community Network via the LCN Global Agenda and surveys.

5. Distribution for Call to Action

Please circulate this **Call to Action** packet by forwarding it to your email distribution lists. GSMP WG/BRG are open to broad participation from any industry group, company, or region. All **'Call to Action'** packets are posted in the GS1 website at:

http://www.gs1.org/services/gsmpp/involve/call_to_action.html

It is also distributed via a GSMP Community email announcement.

6. Timeline:

A kick off/introductory conference call will fully brief all participants of objectives and WG/BRG activities. The first call will be held on **05 March 2009** from **0900–1030 EST (1500-1630 CET)**. The overall duration of this group effort is expected to be approximately **four (4) months**.

7. Participants:

Known Participants:

- Project Manager: **Ulrike Kreysa, GS1 Global Office**
- Sponsor: **GS1 Healthcare Leadership Team**
- Chair: **(To Be Confirmed)**
- GS1 Business Unit Manager: **Scott Gray, GS1 Global Office**
- GS1 Bar Codes Technology Manager: **Chuck Biss, GS1 Global Office**
- GS1 GSMP Process Manager: **Tom Heist, GS1 GSMP**

GS1 Member Organisations (MO) Participants:

Name	Company
Valerie Marchand	GS1 France
Christian Hay	GS1 Switzerland

Supplier Participants:

Name	Company

Retailer Participants:

Name	Company

Data Pool Participants:

Name	Company

Other Participants (Transportation, Logistics, Associations, Governmental etc.):

Name	Company

8. GSMP Process:

For complete information regarding the GSMP (including access to the GSMP Manual), please refer to the website at: <http://www.gs1.org/services/gsmg/overview/>.

9. Sessions

The WG/BRG is responsible for scheduling meetings to accomplish their work. Sessions are defined as face-to-face or physical meetings and teleconferences. All GSMP Sessions include the necessary Anti-Trust cautions as defined by GS1 legal counsel. The Anti-Trust cautions is located on the GS1 website at: http://www.gs1.org/services/gsmg/support/gs1_antitrust.html.

10. Face-to-Face Meetings

The Process Manager schedules face-to-face meetings with reasonable advance notice to allow for proper planning. Face-to-face meetings will cover 2 or 3 days per meeting and will be held in order to speed up the work as much as possible. Participants are expected to cover their own expenses related to travel, accommodation, and time for the physical meetings. Face-to-face meetings will be arranged in GS1 GO locations: **Brussels, Belgium** or **Princeton, NJ, USA, at GS1 Global Healthcare conferences** or may be hosted by participant companies or Member Organizations



11. Teleconferences

GS1 Healthcare Small Instrument Marking Work Group teleconferences will occur every **1st and 3rd Thursday from 09:00-10:30 Eastern Time (1500-1630 CET)**. The kick-off (first) teleconference is scheduled for **5 March 2009**.

12. Agendas and Minutes

GSMP eRoom facilities will be used to support this WG/BRG. The Process Manager is responsible for preparing all agendas and minutes.

Agendas must include:

- Review of the agenda.
- Approval of previous meeting or call minutes.
- Discussion of all pending issues and action items.

Meeting minutes should record:

- The original agenda
- Members, participants, guests, and staff present
- Requests for notation
- Decisions, resolutions, and action items.

13. How to Join

You can join this WG/BRG through the **GS1 Community Room**.

If you are already a GS1 Community Room member:

1. Access the GS1 Community Room at: <http://community.gs1.org/members/>
2. Click on **All Groups**
3. Choose **GSMP Small Instrument Marking** from the list. The group's home page will appear.
4. Click on **Join the Group** in the upper left of the group's home page

If you are NOT a GS1 Community Room member:

1. Apply for GS1 Community Room membership by using our Online Form at: http://community.gs1.org/kmembership_info/person_signup/
2. Once you receive your username and password, follow the directions above to join this WG/BRG.