

ISBT 128 Standard for the Medical Products of Human Origin (MPHO) Unique Identifier

Version 1.0.1

August 2023

Tracking Number ICCBBA ST-026

ISBN-13: 978-1-957177-97-7



Published by: ICCBBA PO Box 11309, San Bernardino, CA 92423-1309 USA

COPYRIGHT, WARRANTY, AND LIABILITY NOTICE

Copyright 2023. ISBT 128 is not in the public domain and is protected by law. Implementation of ISBT 128 requires the end-user to register with ICCBBA and to pay an annual license fee. License fees are established by the ICCBBA Board of Directors to cover the expenses of maintaining and extending ISBT 128, and making available current versions of documents and database tables.

Any use of this document, or the accompanying database tables, by other than registered organizations, or facilities that have obtained their computer software from a registered and licensed developer, is strictly forbidden. Copying any portion of the Standard, or of any accompanying database table, either in electronic or other format, without express written permission from ICCBBA is strictly forbidden. Posting of any portion of the Standard, or of any accompanying database tables, to any online service by anyone other than ICCBBA is strictly forbidden.

ICCBBA provides no representation or warranty that the Licensee's use of ISBT 128 is suitable for any particular purpose and the selection, use, efficiency and suitability of ISBT 128 is the sole responsibility of the Licensee.

ICCBBA's liability is limited to that specified in the ICCBBA License Agreement which is available on the ICCBBA website. Under no circumstances shall ICCBBA's liability to licensee or any third party under any theory or cause of action exceed the current annual license fee payable by the licensee to ICCBBA hereunder, and ICCBBA will in no circumstances be liable for any direct or indirect damages whatsoever, including without limitation special, incidental, consequential, or punitive damages or damages for loss of data, business or goodwill or any other consequential losses of any nature arising from the use of ISBT 128 or the marks.

This document may be translated, without written permission, provided that the translation indicates that it is a translation from an ICCBBA copyrighted document and that ICCBBA is not responsible for the accuracy of the translation.

Editor Karen Moniz, MHA, MT(ASCP)SBB Technical Director, ICCBBA

Standards Committee

Wayne Bolton, BAppSc, MAppSc Standards Committee, APTAG, TAG-IT Chair

AFTAG, TAG-IT CITE

Jolanta Antoniewicz-Papis, PhD EMATAG Chair

Debbie Barnett, MBE, RGN, RM, BSc MBTAG Chair

Suzanne Butch, MA, MT(ASCP)SBB Technical Expert

Jørgen Georgsen, MD

Technical Expert

Martin Hildebrandt, MD RMTAG Chair

Jelena Holovati, PhD, MLT(CSMLS), MT(ASCP) NATTAG Chair

Kathleen Hopping MS, BS ATAG Chair

Eoin McGrath, BA ICCBBA Executive Director

Karen Moniz, MHA, MT(ASCP)SBB ICCBBA Technical Director

Leigh Sims Poston, BS, MT(ASCP)

Technical Expert

Zbigniew Szczepiorkowski, MD, PhD, FCAP CTCLAG Chair

Kelly Tilleman, PhD, MSc ARTTAG Chair

Izabela Uhrynowska-Tyszkiewicz, MD, PhD ETTAG, ITTAG Chair

Table of Contents

1	Intro	oduction	5
	1.1	Purpose	5
	1.2	Scope	5
	1.3	Intended Audience	5
	1.4	Normative Reference	5
	1.5	Other Reference	5
	1.6	Background	5
	1.7	Changes in this Version	3
2	MPI	HO Unique Identifier	7
	2.1	Data elements included in the MPHO Unique Identifier:	7
	2.1.	1 Processing Facility Code [FIN(P)]	3
	2.1.	2 Product Description Code (PDC)	3
2.1.		3 Donation Identification Number (DIN)	3
	2.1.	4 Division Identifier (DIV)	3
_	alala A	Tables	_
18	able 1	Source of MPHO data elements	1
		Figures	
Fi	gure 1	MPHO Unique Identifier Example	7

1 Introduction

1.1 Purpose

The purpose of this document is to provide standards for the coding of the Medical Products of Human Origin (MPHO) Unique Identifier.

1.2 Scope

This document is a supplement to the *ISBT 128 Standard Technical Specification*. It provides the rules for the construction of the MPHO Unique Identifier, a single data item providing globally unique instance identification and designed to optimize the electronic capture of critical MPHO traceability information.

1.3 Intended Audience

The intended audience of this document is electronic health record (EHR) developers, electronic message developers, software developers, regulators, and staff working in facilities collecting, processing, and utilizing MPHO.

1.4 Normative Reference

ISBT 128 Standard Technical Specification (ST-001)

1.5 Other Reference

ICCBBA Website (<u>www.isbt128.org</u>)

Reference Table RT042 – ISBT 128 Data References for use in Electronic Messages

1.6 Background

The ISBT 128 Standard requires that every MPHO labeled with ISBT 128 is identified in a globally unique manner in order to facilitate traceability. The Donation Identification Number (DIN), in conjunction with the Product Description Code (PDC), Division Identifier (DIV), and, in some specific circumstances, the Processing Facility Code [FIN(P)] are the essential data elements to uniquely identify an MPHO and provide the information necessary for traceability.

However, the unique identification of an MPHO product has previously required combining multiple identifiers to provide unique identification. For electronic messaging and electronic health record applications a single unique identifier for an instance is often required. The MPHO Unique Identifier was developed to provide a single identifier built from these critical traceability elements for use in both electronic messaging and electronic health records. The MPHO Unique identifier provides a standardized

mechanism to transmit or store traceability information about any MPHO, regardless of product type, and maintains the integrity of the unique identification by ensuring a direct mapping to the bar coded information on the label.

1.7 Changes in this Version

The following table indicates changes between Version 1.0.0 and Version 1.0.1. Bold print indicates a change to the ISBT 128 Standard; regular print indicates a clarification or additional guidance. When changes were a result of a formal proposal, the number of the proposal is listed in the Rationale column.

Version 1.0.0 vs. Version 1.0.1

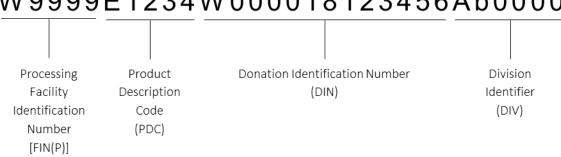
	Version	Version		
	1.0.0 Chapter, Section, Table, or Figure	1.0.1 Chapter, Section, Table, or Figure	Change	Rationale
1.	1.4 & 1.5	1.4 & 1.5	Hyperlinks were added to ST-001 and reference table RT042.	For consistency and to provide a link to the specified Reference Table and document.

2 MPHO Unique Identifier

The MPHO Unique Identifier is constructed from elements critical to the unique identification of an MPHO. The twenty-nine-character code is a combination of the Processing Facility Code (5 characters), Product Description Code (5 characters), Donation Identification Number (13 characters), and Division Identifier (6 characters). The data identifiers for each contributing element are not included in the MPHO Unique Identifier.

Figure 1 MPHO Unique Identifier Example

W9999E1234W000018123456Ab0000



2.1 Data elements included in the MPHO Unique Identifier:

The information held in the MPHO Unique Identifier shall match the information held in corresponding data structures on the product label. For the Division Identifier portion, leading or trailing zeroes may need to be added; see section 2.1.4 for details.

The MPHO Unique Identifier shall be constructed by combining data elements as described below.

MPHO Unique Identifier Element	Length	Source
Processing Facility Identification Number [FIN(P)]	5	Data Structure 033 OR Data Structure 034
Product Description Code (PDC)	5	Data Structure 003 OR Data Structure 034
Donation Identification Number (DIN)	13	Data Structure 001
Division Identifier (DIV)	6	Data Structure 003 OR Data Structure 032

Table 1 Source of MPHO data elements

2.1.1 Processing Facility Code [FIN(P)]

FIN(P) shall be the Facility Identification Number of the facility that assigned the Product Description Code (PDC).

Characters 1-5 of the MPHO Unique Identifier shall be the Processing Facility Code (FIN(P)) if this information is encoded on the product label.

FIN(P) in the MPHO Unique Identifier shall be identical to the FIN(P) in either the Processing Facility Information Code (Data Structure 033) or the Processor Product Identification Code (Data Structure 034) on the product label.

When neither the Processing Facility Information Code nor the Processor Product Identification Code is present on the label then characters 1 to 5 of the MPHO Unique Identifier shall be set to all zeros.

See *ISBT 128 Standard Technical Specification* (ST-001) for complete details on Data Structure 033 and Data Structure 034.

2.1.2 Product Description Code (PDC)

Characters 6 through 10 of the MPHO Unique Identifier shall be the Product Description Code.

The PDC in the MPHO Unique Identifier shall be identical to the PDC held in either the Product Code (Data Structure 003) or the Processor Product Identification Code (Data Structure 034) on the product label.

See *ISBT 128 Standard Technical Specification* (ST-001) for complete details on Data Structure 003 and Data Structure 034.

2.1.3 Donation Identification Number (DIN)

Characters 11-23 of the MPHO Unique Identifier shall be the Donation Identification Number.

The MPHO Unique Identifier DIN shall be identical to the DIN element of Data Structure 001 on the product label.

See *ISBT 128 Standard Technical Specification* (ST-001) for complete details on Data Structure 001.

2.1.4 Division Identifier (DIV)

Characters 24-29 of the MPHO Unique Identifier shall be the Division Identifier.

Divisions are encoded in different ways, with different formats and lengths, across the MPHO range of products. The following rules ensure a consistent mapping between the Division Identifier in the MPHO Unique Identifier and the divisions indicated on the product label.

DIV shall be derived from either the Product Code (Data Structure 003) or the Product Divisions (Data Structure 032).

For products labeled using Data Structure 003 on the label and the twocharacter division information in positions ds of this data structure, DIV shall be the two characters (ds) of the Division Identifier from Data Structure 003, left justified and followed by 4 trailing zeros.

For products labeled using Data Structure 003 on the label and the three-digit division information in positions tds of this data structure, DIV shall be the three digits (tds) of the Division Identifier from Data Structure 003, right justified and preceded by 3 leading zeros.

For products labeled using Data Structure 032 on the label, DIV shall be identical to the six-character data string of this data structure.

See *ISBT 128 Standard Technical Specification* (ST-001) for complete details on Data Structure 003 and Data Structure 032.

P	PUBLICATION

FOR ICCBBA USE ONLY

These links are for internal document control and cannot be used externally:

ST-001 ISBT 128 Standard Technical Specification

10