

	Project/Product: TOF3D	Device Labeling Accessories
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Revision History			
(Doc.-) Version	Author	Date (YYYY-MM-DD)	Revision, Changes, Remarks
V1.0	David Pavlovic	2020-07-21	First final version
V1.1	Matthias Reindl	2021-01-15	Layout for accessories adapted for better barcode quality; Add Service Parts and Accessories

Device Labeling Accessories TOF3D

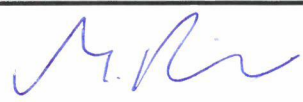
Name	Date (YYYY-MM-DD)	Signature
<i>Created by (MIPM):</i> Matthias Reindl QA/RA Engineer, Equipment Representative	2021-01-15	
<i>Reviewed and Approved by (MIPM):</i> Michael Arnold Technical Director	2021-01-15	
<i>Reviewed and Approved (MIPM):</i> Steffen Burg Project Manager, Product Development; Regulatory Affairs	2021-01-15	

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1. Introduction

1.1 Purpose

This document defines the general specifications of the accessories labels (stickers).

1.2 References

1.2.1 Referenced standards for symbol definitions

Standard	Title of the referenced standard
ISO 15223-1:2016 (ed3.0)	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
ISO 15223-1:2020 (Proposal)	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
Directive 93/42/EEC	EU: COUNCIL DIRECTIVE 93/42/EEC concerning medical devices (MDD)
Regulation (EU) 2017/745	EU: Regulation (EU) 2017/745 on medical devices (EU-MDR)
Regulation (EU) 2017/745 Annex 1/Chapter 3	EU: Regulation (EU) 2017/745 on medical devices (EU-MDR) Annex 1 - General safety and performance requirements Chapter 3 - Requirements regarding the information supplied with the device
DIRECTIVE 2012/19/EU	DIRECTIVE 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on waste electrical and electronic equipment (WEEE)
21 CFR Part 800 - 898	USA: Code of Federal Regulation Title 21 – Food and Drugs, Parts 800 to 898 – Medical Devices
21 CFR Part 801	USA: Code of Federal Regulation Title 21 – Food and Drugs, Parts 801 - Labeling
21 CFR Part 830	USA: Code of Federal Regulation Title 21 – Food and Drugs, Part 830 – Unique Device Identification
ANSI/HIBC 2.6	THE HEALTH INDUSTRY SUPPLIER LABELING STANDARD FOR PATIENT SAFETY & UNIQUE DEVICE IDENTIFICATION (UDI)

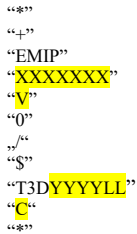
1.2.2 Referenced documents

- Instruction for Use (IFU) of TOF3D
- Service manual of TOF3D
- List of Standards of TOF3D
- List of REF, GMDN, UMDNS, Class and UDI Information

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2. Device Labeling of Accessories and Service Parts of TOF3D

2.1 Symbols with description

Symbol	Description	Source of Symbol: Referenced standard (basic standard and no. of Symbol)
TOF3D 	Brandname	MIPM
	Company Logo of MIPM	MIPM
REF	Product reference / part number	ISO 15223-1 (ISO 7000-2493)
LOT	Batch code: T3DYYYYLL <u>Structure:</u> - “T3D” (fix 3-digits): device ID - “YYYY” (variable 4-digits, numeric): year of manufacturing - “LL” (variable 2-digits, numeric): production LOT no./Batch no. of that particular year (of manufacturing)	ISO 15223-1 (ISO 7000-2492)
MD	Medical Device	ISO 15223-1:2020 (Proposal)
	Part included in a recovery / recycling process	WEEE (EN 50419)
	CE Marking	Directive 93/42/EEC (MDD) Regulation (EU) 2017/745 (EU-MDR)
L: Vx.x	Label Version: Vx.x x.x: corresponds to label version	MIPM
Rx only	Caution: Federal Law in the United States restricts the device to sale by, or on the order of a physician.	21 CFR Part 801 Subpart D
	HIBC Code in format Data Matrix (variable characters are highlighted) - Start Code after: - HIBC Supplier Labeling Flag Character (fix 1-digit): - Labeler Identification Code (LIC) (fix 4-digits, alphanumeric): - Labelers Product/Catalog Number (fix 7-digits, numeric): - Variant code (variable, 1-digit, alphanumeric): - Unit of Measure ID (fix 1-digit, numeric): - Data Delimiter (fix 1-digit): - Lot Number Reference Identifier (fix 1-digits): - Lot Number (Structure of LOT explained above): - Check Character by Modulo 43 (variable, 1-digit): - End Code before:	 ANSI/HIBC 2.6

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2.2 Accessories

2.2.1 Temperature sensor

REF:	Name:
5750106	Temperature sensor

2.2.1.1 Product Label

Position: a flag on the cable near by the connector to TOF3D Main Cable

Dimensions (Length x Height): 12 x 75 mm; Tolerance ± 2 mm

Color of Label: White

Color of Print: Black

Label Version: V1.1



2.2.2 Hand adapter

REF:	Name:
5750100	Hand adapter

2.2.2.1 Product Label

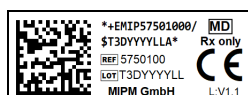
Position: on Hand adapter

Dimensions (Length x Height): 12 x 33 mm; Tolerance ± 2 mm

Color of Label: White

Color of Print: Black

Label Version: V1.1



2.2.1 IV-pole holder Variant A - Premium

REF:	Name:
5750110	IV-pole holder Variant A - Premium

2.2.1.1 Product Label

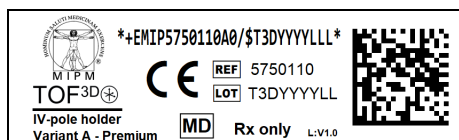
Position: on IV-pole holder

Dimensions (Length x Height): 18 x 60 mm; Tolerance ± 2 mm

Color of Label: White

Color of Print: Black

Label Version: V1.0



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2.2.1 IV-pole holder Variant B - Standard

REF:	Name:
5750110	IV-pole holder Variant B - Standard

2.2.1.1 Product Label

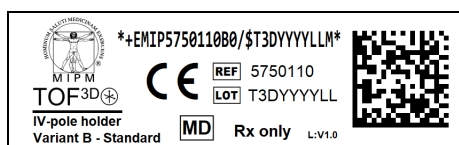
Position: on IV-pole holder

Dimensions (Length x Height): 18 x 60 mm; Tolerance ± 2 mm

Color of Label: White

Color of Print: Black

Label Version: V1.0



2.3 Service Parts

2.3.1 USB interface cable

REF:	Name:
5750103	USB interface cable

2.3.1.1 Product Label

Position: a flag on the cable near by the USB connector

Dimensions (Length x Height): 12 x 75 mm; Tolerance ± 2 mm

Color of Label: White

Color of Print: Black

Label Version: V1.0

