Symbols Glossary
Orthodontic Metal Brackets

The symbols used on the product labeling are internationally recognized and provide important information regarding safe use, handling, and regulatory compliance. Refer to the glossary below for the definition of each symbol appearing on labeling, packaging, or Instructions for Use.

1. **The following are per ISO 15223-1** (*References as indicated*).

Symbol Standard Reference	SYMBOL TITLE – Explanatory Text
 Ref. 5.1.1	**Manufacturer**: Indicates the medical device manufacturer.
 Ref. 5.1.2	**Authorized representative in the European Community / European Union** Indicates the authorized representative in the Eurpean Community / European Union.
 Ref. 5.1.3	**Date of manufacture:** Indicates the date when the medical device was manufactured.
 Ref. 5.1.5	**Batch Code:** Indicates the manufacturer's batch code so that the batch or lot can be identified.
 Ref. 5.1.6	**Catalogue or model number:** Indicates the manufacturer's catalogue number so that the medical device can be identified.
 Single Use Ref. 5.4.2	**Do not re-use/single patient use:** Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
 Ref. 5.4.3	**Consult instructions for use:** Indicates the need for the user to consult the instructions for use.
 Ref. 5.7.7 MDR 2017/745 Annex 1 23.2(q)	**Medical Device:** Indicates that the device is a medical device.

2. **The following are per MDR EU 2017/745** (*References as indicated*).

Symbol Standard Reference	SYMBOL TITLE – Explanatory Text
CE MDR 2017/745 Article 2 and Annex V	**CE Marking of Conformity:** Marking by which a manufacturer indicates that devices in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legistaion proviving for its affixing.

3. **Other symbols**

Symbols Not Derived from Standards	
Ni Cr Contains Nickel and/or Chromium	**Product contains Nickel and/or Chromium** FDA 21 Part 872 Sec. 872.3710 Base metal alloy.

105-7310-01 (DOC-7598) Ver. 0

Approved By:

(CO-806) IFU Supplementary Documents

Description

Initial release.

Justification

Response to TUV TF Review Questions.

Assigned To:	Initiated By:	Priority:	Impact:
Maureen Janssen	Maureen Janssen	Urgent	Major

Version History:

Author	Effective Date	CO#	Ver.	Status
Maureen Janssen	September 5, 2025 7:53 AM PDT	CO-806	0	Published