[Manufacturer's Letterhead]

Açıklamalı [AB1]: The prepared declaration must be submitted on the letterhead of the manufacturer and must include the document name, code, publication date, revision number and revision date.

EU DECLARATION OF CONFORMITY

We, [Name of Manufacturer] at [Address of Manufacturer], declare under our sole responsibility that the medical device(s) described below complies with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council on medical device(s) and other relevant Union legislation.

Manufacturer:

Açıklamalı [AB2]: ANNEX IV
1. The name, registered trade name or registered trademark of the manufacturer and, if applicable, of its authorized representative and, if already issued, its CCN as referred to in Article 31 and the address of its registered place of business where they can be reached and located;

Name: [Name of Manufacturer]

Registered Trade Name or Trademark: [Registered Trade Name or Trademark]

Authorized Representative (if any): [Name of Authorized Representative]

Address of Authorized Representative: [Address of Authorized Representative]

Manufacturer's Registered Business Address: [Manufacturer's Registered Business Address]

Açıklamalı [AB3]: All information about the producer must match the information in the official records. In particular, the title and address must be fully specified.

SRN: [SRN]

Açıklamalı [AB4]: Enter your identifier number provided to you upon registration in the EUDAMED system.

We declare that this EU Declaration of Conformity has been prepared under the sole responsibility of the manufacturer.

Açıklamalı [AB5]: ANNEX IV
2. a declaration that the EU declaration of conformity has been drawn up under the sole responsibility of the manufacturer;

Basic UDI-DI (Unique Device Identifier - Device Identifier): [Basic UDI-DI]

Açıklamalı [AB6]: ANNEX IV
3. Basic UDI-DI as referred to in Part C of Annex VI;

Device Information:

Açıklamalı [AB7]: ANNEX IV
4. the intended use, together with other precise references, such as product name and trade name, product code, catalogue number or, where applicable, photograph, which allow identification and traceability of the device covered by the EU declaration of conformity. Information enabling identification and traceability, excluding the product name or trade name, may be provided by the Basic UDI-DI referred to in point 3;

Açıklamalı [AB8R7]: If a declaration is prepared for more than one product group, this field can be tabulated and added to the end of the declaration.

Intended Use: [Intended Use]

Product Name: [Product Name]

Product Code: [Product Code]

Catalog Number: [Catalog Number].

Photo: [Photo (if available)]

Sterile: [Sterilization Method if applicable]

EMDN Codes: [Related Code(s)]

MDR Codes: [Related Code(s)]

Risk Class: [Risk Class of the Device according to Annex VIII]

Açıklamalı [AB9]: Specify the risk class, including the rule to which it relates.

We declare that the device covered by this declaration complies with Regulation (EU) 2017/745 and, where applicable, other relevant Union legislation requiring the issue of an EU Declaration of Conformity.

References to Common Specifications (where applicable):

Harmonized Standards: [List of Harmonized Standards]

MDCG Guidelines: [List of MDCG Guidelines]

Notified Body Information (if applicable):

Notified Body Name: [Notified Body Name]

Identification Number: [Identification Number]

Description of Conformity Assessment Procedure: [Description of Conformity Assessment Procedure]

Certificate(s) issued: [Certificate(s) issued]

Additional Information (if available): [Additional Information]

Place and Date of Publication:

Place: [Place of Publication]

Date: [Publication Date]

This declaration has been issued on behalf of [Name of Manufacturer] by

Name: [Name of Signatory]

Position: [Signatory's Position]

Signature: [Signature]

[Signatory's Written Name]

[Date Signed]

[End of Statement]

Açıklamalı [AB10]: ANNEX IV
6. a declaration that the device covered by the present declaration complies with this Regulation and, where applicable, with any other relevant Union legislation requiring the issue of an EU declaration of conformity;

Açıklamalı [AB11]: Standards should be added by indicating the current year of publication. Example: EN ISO 14971:2019/A11:2022.

Açıklamalı [AB12]: MDCG Guidelines should be added with the current revision information. Example: MDCG 2020-3/Rev.01

Açıklamalı [AB13]: ANNEX IV
8. Where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure carried out and identification of the certificate or certificates issued;

Açıklamalı [AB14]: ANNEX IV
9. Additional information where applicable;

Açıklamalı [AB15]: ANNEX IV
10. Place and date of issuance of the declaration, name and position of the person signing and on whose behalf the person is signing, signature.

Açıklamalı [AB16]: According to the ÜTS System; The user information signing the document must be the same in the system and the document.
Stamp information must also be included in the signature.