SAMPLE IDENTIFICATION

Rev. D

Instructions:

- ***EACH FIELD IS MANDATORY, if applicable.***
- *If you are submitting a series of items, please use one of this form for each sample*
- *Fill in carefully all the fields as they will appear in the FINAL REPORT - If you do not have the required data, or is not applicable for you, please indicate "**N/A**"*
- *Empty fields will appear as "**NOT PROVIDED**"*
- *By transmitting this information you verify that all information contained in this document is, to the best of your knowledge, factual and can be used for the purposes of conducting the approved studies and preparing a final report*

For any further information please contact: Coronati Consulting Laboratory staff: sample@coronaticonsulting.it

RESERVED TO THE CUSTOMER

Customer:	
Other company involved:	
Quotation Nr.:	
Customer purchasing order:	

TYPE OF TEST REQUESTED *(specify which tests should be performed - this text will not appear in the final report)*

REGULATORY REQUIREMENT

Type of accreditation requested:		
Competent Authority who request GLP test:		

Information on regulatory compliance:

- *Please note that some accreditation may not be applicable to all tests requested, for the list please follow this link: https://www.coronaticonsulting.it/certificati/*
- *Just some biocompatibility tests may be accredited GLP; for more information please contact us*
- *For Good Laboratory Practice (GLP) studies you must specify in the upper field the competent authority who request the test*
- *For ACCREDITED test the number of samples must be the same required by the reference standard. If the number is less than required, the test method will not be accredited*
- *If the number of samples is not specified in the test method or in the reference standard, it is under the responsibility of the customer choosing it*

SAMPLE IDENTIFICATION

Commercial name:		
Type of Device and other details *(shipping, treatments/washes undergone, ..):*		
Composition and/or materials:		
Code (REF):		
LOT or Batch Nr.:		
Manufacturing date:		
Expiry date:		
Sterilization method:		
Sterilization batch:		
Sterilization date:		
Sterilization facility:		
Degassing time :		
Type of contact with the patient:		
Duration contact with the patient:		
Storage after reception @Coronati:		

NOTES REGARDING TESTS *(this text will not appear in the final report)*

SAMPLE DISPOSAL

- TESTED DEVICES (if possible)

Even if you choose "return", the conditions after the test may not allow us to send them back. Ask for more details.

- NOT TESTED DEVICES (if there are)

If we do not receive any information about the final treatment of the samples, these will be automatically disposed of as waste

AGING BY THE CUSTOMER

Sample aged by Customer:

If **YES**, complete aging conditions data below

Type:	
Temperature:	
Duration:	

Coronati consulting lab

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Rev. D

ONLY FOR EO/ECH/EG RESIDUE TESTS

Device Category according to ISO 10993-7:	
Type of extraction:	
Temperature and time of extraction:	
Mode of extraction:	
Type of patient:	

ONLY FOR BIOCOMPATIBILITY TESTS

(a.e. Cytotoxicity, Intracutaneous reactivity, Sensibilization GPMT, Acute systemic toxicity, Haemocompatibility…)

Sample thickness (mm):	
Sample weight (g):	
Sample totale surface (cm^2) to be tested:	
Internal volume/capacity (mL):	
Does the device contain heat labile or heat sensitive materials at high temperature (50°C)?	

FOR IN VIVO STUDIES - by selecting this checkbox, the Customer declares under its responsibility that no other studies of the same type have been already performed on the test item ☐

EXPIRY DATE - if is not available, the Customer declares under its responsibility that samples are to be considered stable for the aim of the study for at least: _____ months from the date of _____

ONLY FOR LAL TESTS

Production batch size: _____

In case the number of samples does not respect those foreseen by the production lot, or the lot number is not specified, the test report will be credited only if 10 samples are tested

Production batch size	Number of samples on which perform the LAL Test
<30	2
30 ÷ 100	3
>100	3% until max 10 pcs

Compiler name:	
Compiler e-mail:	
Compilation date:	

This document must be sent completed in PDF format to the e-mail address sample@coronaticonsulting.it and accompany the sample. The beginning of the laboratory activities is bound to the arrival of the duly completed form.
You can use the buttons below.

Send this form by e-mail

Print a copy

Send samples to **Coronati Consulting srl** at the following address

Via L. Gavioli, 3
41037 Mirandola
(MO) Italy

RESERVED TO CORONATI CONSULTING

No. acceptance: *Reviewed by:* ◯ *Conform* ◯ *Not conform*