Title:	Sponsorship & Supplier Quality Agreements	**Document No.:**	YGD 0404
Effective:	30/06/2022	**Revision:**	4
Revised By:	Laxmi	**Approved By:**	Vengatesh

1.0 OBJECTIVE

The objective of Supplier Quality agreement & Sponsorship agreement procedures is to describe complete details of requirements for these two agreements between two parties including supplier/ manufacturer (hereafter, YTY group) and the buyer/sponsor/importer.

2.0 SCOPE

This procedure is applicable to Quality Management System, Quality control, Quality assurance, Personnel's responsibility, Incoming raw material, Process requirement, Changes of products and processes, Product realization, Financial condition, Shipping, Registration, Documentation, Pre- and post-supplying, Marketing authorization, device-related events and Advisory notices.

3.0 REFERENCE

1) MDSAP AU G0002.1.004_revised 2017-04-13
2) Australian Regulatory Guidelines for Medical Devices (ARGMD).
3) Australian Therapeutic Goods Act 1989.
4) Brazilian Resolution – RDC No. 16 of March 28, 2013.
5) Japanese Pharmaceutical and Medical Device Agency (PMDA).
6) Japanese Marketing Authorization Holder (MAH).
7) Health Canada Medical Device Regulation.
8) Medical Device Directive 93/42/EEC / Regulation (EU) 2017/745

4.0 DEFINITION

Nil

YTY GROUP
CONTROLLED COPY
NO DUPLICATION
VALID ONLY IF STAMPED RED

5.0 RESPONSIBILITY

5.1 Document Controller
Document Controller is responsible for updating, distributing and control of the Supplier Quality agreement and Sponsorship agreements.

5.2 Manager DC & RA
Manager DC & RA is responsible for authorizing changes and approving the Supplier Quality agreement and Sponsorship agreements.

5.3 Senior Executive of Regulatory Affairs
Senior Executive is responsible for providing the information in Supplier Quality agreement and Sponsorship agreements.

6.0 PROCEDURE

6.1 The Supplier Quality agreement and Sponsorship agreement will be updated as and when new products or procedures are included.

6.2 The Product Specifications are tabulated from procedures for different types of gloves manufactured.

6.3 YTY manufacturer will notify Auditing organization upon proposed changes to marketed devices or to manufacturer's OMS, to ensure all aspects complies with regulatory requirements.

6.4 YTY manufacturer ensures arrangements for device marketing authorization and facility registration from authorities.

6.5 YTY as a Legal Manufacturer ensures that the medical devices shall meet certain requirements, which are specified in the quality agreement and establishes the required documentation as per EU MDR Regulation 2017/745.

7 RECORDS

7.1 YGD 040401- Australia (Sponsorship agreement for Australia)
7.2 YGD 040402-Brazil (Sponsorship agreement for Brazil)
7.3 YGD 040403-Japan (Sponsorship agreement for Japan)
7.4 YGD 040404 –Japan (Supplier Quality agreement for Japan)
7.5 YGD 040405-Canada (Supplier Quality agreement for Canada)
7.6 YGD 040406-Australia (Supplier Quality agreement for Australia)
7.7 YGD 040407-Brazil (Supplier Quality agreement for Brazil)
7.8 YGD 040408-Europe (Supplier Quality agreement for Europe)
7.9 YGD 040409-Europe (Legal Manufacturer and Distributor Quality Agreement)

YTY GROUP
CONTROLLED COPY
NO DUPLICATION
VALID ONLY IF STAMPED RED

Title:	Sponsorship & Supplier Quality Agreements	**Document No.:**	YGD 0404
Effective:	30/06/2022	**Revision:**	4
Revised By:	Laxmi	**Approved By:**	Vengatesh

Reason For Change

Old Revision	*Current Revision*	*Effective Date*	*Page Affected*	*Revision Description*	*Provided By*	*Approved By*
Nil	0	26/10/2018	All	New Procedure	Mohadeseh	Punitha
0	1	19/11/2018	All	Revise procedure as per TUV audit finding	Mohadeseh	Punitha
1	2	25/10/2019	Page 2	Clause 6 Records Renumbering	Pei Leng	Punitha
2	3	04/01/2021	Page 1 & 2	Add reference clause 3.0 and record clause 7.8	Nurfatin	Punitha
3	4	30/06/2022	Page 2	Add clause 6.5 and record clause 7.9	Laxmi	Vengatesh

YTY GROUP
CONTROLLED COPY
NO DUPLICATION
VALID ONLY IF STAMPED RED