PROCEDURE TEMPLATE

Procedure on Demonstration and Evaluation Products

# PURPOSE

This Procedure establishes requirements to follow Alcon’s *The Lens* policy requirements that govern provision of *Demonstration Products* and *Evaluation Products*, including medicinal *Products,* to *Healthcare Professionals* (“*HCPs*”) or *Healthcare Organizations* (“*HCOs*”) free of charge for demonstration or evaluation purposes. This procedure also reflects any additional and/or stricter requirements that apply under the local law or *Industry Code*. Local requirements are to be considered and applied in conjunction with *The Lens* requirements.

# SCOPE

This Procedure applies to all relevant [Insert company name] associates (“Associates”) working in ***[insert Country]*** who participate in any way in providing (or tracking the provision of) *Demonstration* *Products* and *Evaluation Products*, including medicinal *Products*, to *Customers*.

# RESPONSIBILITY

[Insert company name] who participate in any way in providing (or tracking the provision of) *Demonstration Products* and *Evaluation* *Products* to *HCPs* or *HCOs* are responsible for following this Procedure and for overseeing the actions of third parties retained to assist Alcon with these activities.

# DEFINITIONS

# Terms that are initial capitalized and italicized are defined in Alcon’s *The Lens* glossary.

# REQUIREMENTS

* 1. **Single-Use Products (Consumables)**

1. **Quantity limits for Single Use Products**

* **Demonstration Products** – Consistent with *The Lens* requirements, consumable *Demonstration* *Products* may be provided only in quantities reasonably necessary for the intended demonstration purpose. ***INSERT or REFERENCE applicable local process for establishing local quantity limits on distribution of single use Products provided for demonstration purposes, whether based on internal or external legal or code limits.***
* **Evaluation Products** – Consistent with *The Lens* requirements, consumable *Evaluation Products* (both devices and medicinal *Products*) may be provided only in quantities reasonably necessary to meet *Patient/Consumer* care needs, or to permit the recipient to evaluate the *Product* adequately for future use. ***INSERT or REFERENCE applicable local process for establishing local quantity limits on distribution of single use Products for evaluation purposes, whether based on internal or external legal or code limits.***

1. **Tracking of Single-Use Products**

* **Reasons for Tracking** *–* Single-use *Demonstration* *Products* and *Evaluation* *Products,* including medicinal Products, must be adequately tracked by type and quantity, and adequate records maintained, to:
* Allow traceability of *Products* in the event of a recall
* Verify that annual quantity limits are not exceeded for any given *Customer*, and
* Allow accurate company record-keeping, and disclosure to comply with local disclosure requirements. ***[Insert last clause if local disclosure requirements apply]***

# Tracking processes for single use Products

# Prescription *Products* – *Insert local process for adequate tracking if single-use prescription Products are provided in the local market for demonstration or evaluation purposes; indicate any differences in local tracking requirements for different:*

* *Types of Products (devices/medicinal Products, evaluation/demonstration, non-sterile Products used for demonstration, etc.)*
* *Types of Customers*
* *Methods of distribution (tracking may differ for Products distributed from a central location versus Products distributed by sales representatives, etc.)*

# Non-prescription Products – *Insert local process for adequate tracking for single-use non-prescription Products provided in the local market for demonstration or evaluation purposes; indicate any differences in local tracking requirements for different:*

* *Types of Products (prescription/non-prescription, devices/medicinal Products, evaluation/demonstration, non-sterile Products used for demonstration, etc.)*
* *Types of Customers*
* *Methods of distribution (tracking may differ for Products distributed from a central location versus Products distributed by sales representatives, etc.)*

***Insert this Section if placement of multiple use equipment for evaluation is permitted locally***

* 1. **Multiple-Use Devices (equipment) placed for evaluation** – ***INSERT or REFERENCE*** *local process for placing multiple-use Alcon devices (e.g., surgical equipment) for evaluation purposes at HCP or HCO facilities; process should cover at least the following information:*
* *The equipment placement period must not exceed: \_\_\_\_\_* ***[insert local time limit]****. If an extension is needed, advanced documented approval is required from* ***[designate who in senior leadership must approve]****.*
* *Labeling requirements*
* *How the terms of the placement are to be documented, with terms to include the duration of the evaluation period and confirmation that the legal title to the equipment remains with you.*
* *Process for collecting the contracts, monitoring the contracts for pick up dates, and arranging for appropriate document retention for future reference]*
* *Local process for accurately tracking equipment placement and expiration dates*
* *Process for promptly removing equipment from the HCP’s or HCO’s facility by the end of the evaluation period (unless an agreement to purchase or lease the equipment has been executed by the Customer).*
* *Process for monitoring placement of multiple-use Evaluation Product inventory on at least a quarterly basis to verify where evaluation equipment is located and to verify compliance with documented pick up dates.*

1. **REFERENCES** – *The Lens* policy and reference table