SRI TRANG GLOVES (THAILAND) PUBLIC COMPANY LIMITED
Registration number 0107562000106
Headquarter: No. 110, Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230 Thailand
Tel: (66) 74-471-471
Fax: (66) 74-291-650
Office: No. 10 Soi 10, Phetkasem Road, Hat Yai, Hat Yai, Songkhla 90110 Thailand
Tel: (66) 74-344-663
Fax: (66) 74-344-677, 74-237-423, 74-237-832

บริษัท ศรีตรังโกลฟส์ (ประเทศไทย) จำกัด (มหาชน)
ทะเบียนเลขที่ 0107562000106
สำนักงานใหญ่: เลขที่ 110 ถนนกาญจนวนิช ตำบลพะตง อำเภอหาดใหญ่ จังหวัดสงขลา 90230 ประเทศไทย
เบอร์โทรศัพท์: 074-471-471
เบอร์แฟกซ์: 074-291-650
สำนักงาน: เลขที่ 10 ซอย 10 ถนนเพชรเกษม ตำบลหาดใหญ่ อำเภอหาดใหญ่ จังหวัดสงขลา 90110 ประเทศไทย
เบอร์โทรศัพท์: 074-344-663
เบอร์แฟกซ์: 074-344-667, 074-237-423, 074-237-832

PMCF Plan 2021

Post-Market Clinical Follow-up Plan for the year 2021

1. Scope

The scope of the PMCF Plan is to give a guideline on how to update the clinical evaluation and risk management based on a systematic approach of checking post-market clinical and non-clinical information sources.

2. Principles & Normative reference

MDR 2017/745 states:

"(a) the general methods and procedures of the PMCF to be applied, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of clinical data;

(b) the specific methods and procedures of PMCF to be applied, such as evaluation of suitable registers or PMCF studies;

(c) a rationale for the appropriateness of the methods and procedures referred to in points (a) and (b);

(d) a reference to the relevant parts of the clinical evaluation report referred to in Section 4 and to the risk management referred to in Section 3 of Annex I; 5.5.2017 EN Official Journal of the European Union L 117/165

(e) the specific objectives to be addressed by the PMCF;

(f) an evaluation of the clinical data relating to equivalent or similar devices;

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(g) reference to any relevant CS, harmonised standards when used by the manufacturer, and relevant guidance on PMCF; and

(h) a detailed and adequately justified time schedule for PMCF activities (e.g. analysis of PMCF data and reporting)

to be undertaken by the manufacturer."

MEDDEV 2.12/2 rev.2 Post market clinical follow-up studies – January 2012 states: "PMCF studies are one of several options available in post-market surveillance and contribute to the risk management process."

Further it defines PMCF Plan as "The documented, proactive, organised methods and procedures set up by the manufacturer to collect clinical data based on the use of a CE-marked device corresponding to a particular design dossier or on the use of a group of medical devices belonging to the same subcategory or generic device group as defined in Directive 93/42/EEC. The objective is to confirm clinical performance and safety throughout the expected lifetime of the medical device, the acceptability of identified risks and to detect emerging risks on the basis of factual evidence." and "PMCF studies may not be required when the medium/long-term safety and clinical performance are already known from previous use of the device or where other appropriate post-market surveillance activities would provide sufficient data to address the risks."

Standards used can be found in the list of applicable standards for Nitrile and Natural Rubber Latex examination gloves in their latest versions, but to name the most prominent prototypes, the standards of the EN 455 series and ISO 10993 series are major contributors to ensuring the performance and safety of the medical devices. For the risk management

design, the standard ISO 14971 in its latest version shall be used, while the general quality management system shall follow ISO 13485.

Summary: The PMCF Plan outlines the methods and chosen frames for updating the clinical evaluation on a regular basis, incorporating new sources of information and checking on identified risks and the correct assessment of those in the risk management activities.

Examination gloves, both sterile and non-sterile, are used since centuries and the materials NBR and NR have been well established with several hundred billion gloves per year consumed all over the world. From this fact and the current post-market surveillance data available, there might be the possibility explored, that PMCF studies are not necessary to evaluate the safety, quality or performance of that particular medical devices. Further details can be found in subsequent sections.

3. Methods

Input from passive information sources

The following information sources shall be used to generate data for both, risk management and clinical evaluation. In particular, the post-market surveillance in form of complaint handling and evaluation of authority reports are of essential importance to identify new risks and the updating of the clinical evaluation. Further market activities include competitor analysis, literature, conferences, discussion with regulators and notified bodies, customer & end-user interview, review of actions against similar or identical products published by authorities and regulators and review of public incident reporting databases.

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For all mentioned methods, both case studies and/or statistical analysis shall support the understanding and are allowed to be used. Limitations shall only exist in the context of patient data, which shall be anonymized in order to protect the patients identity according to national and international data protection acts.

For preclinical testing, harmonized standards and common specifications shall be preferred, if available. Otherwise, standards from other regulated markets (e.g. United States of America) may also be used.

Input from proactive collection of information

To fulfill the requirement of proactive post-market surveillance activities, a new process is established, starting in accordance with the new timetable of section 4. The process will use contact data collected with the database for technical documentation exchange and shall include proactive questionnaires in electronic form, that are specific to one or more topics, which are in focus of assessment. Customers will be questioned for their experience and user exchange for the topics, so that a proactive exchange is started. Customers will be provided information material to ensure a certain common level of understanding is factually present, before the questionnaire is activated. This ensures, that the quality of the feedback is sufficient for analysis.

4. Plan & Time schedule

Action	Timeframe	Desired Outcome
Complaint analysis	Without undue delay after incoming complaint information	Proper case studies and statistics
Competitor analysis	At least once a year	Comparison & studying of advancement of state of the art
Literature review	At least all two years	Proper literature section in the clinical evaluation report
Interviews with users, customers, conferences, regulators and notified bodies	During trade shows, fairs, customer visits and inspections	Advanced understanding of changed settings, applications, experiences, complaints, technologies and regulations
Review of authority reports & actions taken by regulators	Without undue delay after receiving an authority reports or learning about an action taken by a regulatory	Learnings from case studies
Review of public incident reporting databases	Once a year	Learnings from case studies
Preclinical Data & Testing	Per Demand	Preclinical assessments shall help to study product performances under standardized and objective settings.
Proactive questionnaires	Once a quarter	Raising the level of understanding and awareness on customer

		side & getting feedback on more complex and rare product deficiencies

The protocol for documentation of each process shall be defined in the quality management system by latest May 2020. Provided records may be optional or mandatory, as to the level of appropriateness.

5. References to the Clinical Evaluation Report

The PMCF process is described in the Clinical Evaluation Report and covers the conclusion, present in section 7 of the PMCF Plan. Changes in the PMCF Plan shall be discussed in the Clinical Evaluation Report and shall be justified.

6. References to the Risk Management

Residual risks deriving from the risk analysis and risk/benefit analysis have to be evaluated in the post-market surveillance activities. Risks that are identified by case studies or statistics and have not yet been evaluated or have been evaluated the last time before a significant update occurred, have be evaluated. The input of section 4 shall be used to update the Risk Management File and the outcome of the Risk Management shall influence the conclusion in the Clinical Evaluation and be recorded in the Clinical Evaluation Report.

7. Rationale for Appropriateness

Given that the products are used for decades and new technologies are rare and mostly rather focus on saving costs than exploring new materials, product features or alike, the design, production and usage of these low-risk medical devices can be seen as established.

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Therefore, and because the post-market surveillance until today did not show any severe hazards deriving from usual product applications, it can be assumed to our best knowledge that a Post-market clinical follow-up study may not be necessary, unless there is a significant change in the product characterization, technology or application.

The actions of section 4 are seen as appropriate for the clinical evaluation of sterile and non-sterile examination gloves, but both, section 4 and this rationale, shall be subject to change in case of significant changes in the product characterization, technology or application.

8. Conclusion

The PMCF Plan consist of several actions to be taken on demand or regularly to ensure the Clinical Evaluation and its record, the Clinical Evaluation Report are regularly updated. Nevertheless, there was no need identified for having Post-Market Clinical Follow-up studies.

Established and Approved by

This document is valid without the signatures.

_____	_____	_____
Mr. Daniel Stocker	Mrs. Sineenat Utanpun	Mr. Nattawut Promthong
Group of Quality and R&D Manager	Quality System Manager	Senior Assistant Technical Product Management
Date: 01/01/2021	Date: 01/01/2021	Date: 01/01/2021