MEDIFACTIA AB — CTT REPORTING SYSTEM

Terms and Conditions of Use (“Agreement”)

Last revised: June 11, 2026

PLEASE READ THESE TERMS AND CONDITIONS CAREFULLY BEFORE USING THE CTT REPORTING SYSTEM.

Medifactia AB, a Swedish company registered under the laws of Sweden, registration number 556919-4409 (“Medifactia”), provides and makes available the CTT Reporting System (the “Agreement”) under these Terms and Conditions. As used herein, “you” or “users” refers to MEDICAL PROFESSIONALS only. By using the Tool and clicking the “I Agree” button, you unconditionally agree to be bound by this Agreement and our Privacy Statement. If you do not accept these terms, you must not access or use the Tool.

The Tool is currently provided free of charge. Medifactia reserves the right to introduce fees in the future. Defects or disruptions should be reported promptly to Medifactia via info@medifactia.com or +46 (0)8 460 072 06 (weekdays 08:00–17:00, excluding Swedish public holidays).

1. MODIFICATION OF THIS AGREEMENT

Medifactia reserves the right to update or modify this Agreement at any time without prior notice. Continued use of the Tool after any such change constitutes acceptance of the revised Agreement. Users are encouraged to review this Agreement periodically.

2. INTENDED AUDIENCE

The Tool is intended exclusively for use by qualified healthcare professionals (HCPs), including radiologists, gastroenterologists, physicians, and other authorised clinical practitioners. The primary intended user is a qualified radiologist who has determined the radiopaque marker count from a plain abdominal X-ray. It must not be used by laypersons or patients. If you are not an HCP, you must not use this Tool.

The Tool is an informational calculation and reporting aid. It must only be used by HCPs who independently verify all input data and exercise their own clinical judgement. It does not replace clinical evaluation or professional medical expertise.

A prerequisite for use is that Medifactia® Transit-Pellets radiopaque markers were used in accordance with the applicable Instructions for Use. Use with any other marker product falls outside the intended use and may produce invalid results, for which Medifactia AB accepts no liability. Use with other marker products constitutes a breach of this Agreement.

3. INTENDED USE AND LIMITATIONS

The Tool calculates and reports total and segmental oro-anal colonic transit time (CTT) from a clinician-entered count of retained radiopaque markers, using the established published formula (M ÷ 10), and presents the result alongside established, gender-specific normative reference values for the clinician’s reference. Reference values apply to individuals aged 18 years and older. The Tool is not intended for use in assessing colonic transit time in individuals under the age of 18, as

the reference values do not apply to this population and results outside the validated range may be misleading.

The Tool is a transparent calculation and formatting aid only. It:

- does not acquire, process, or analyse medical images or physiological signals;
- does not interpret clinical findings;
- does not generate a diagnosis, prognosis, or treatment recommendation;
- automates a manual arithmetic calculation routinely performed in clinical practice and introduces no autonomous clinical decision logic;
- does not modify or supplement clinical input beyond formatting and presenting the entered data and calculated result.

All clinical interpretation and patient management decisions remain the sole responsibility of the treating clinician.

The Tool has not been submitted for regulatory clearance or approval as a medical device and is not CE-marked or FDA-cleared as a medical device. It is positioned as a calculation and reporting aid that falls outside the definition of a medical device under EU MDR 2017/745 and applicable FDA regulations.

4. REPORT TRANSPARENCY AND VERIFICATION

Every report generated by the Tool will include:

- the raw clinician-entered marker count;
- the formula applied (M ÷ 10);
- the calculated total and segmental CTT values;
- the normative reference table with source citation.

This enables full independent verification of results by the clinician. No conclusions are generated that cannot be independently verified from the displayed inputs and published references. The clinician is responsible for reviewing and confirming all output before it is used in any clinical decision.

5. USER OBLIGATIONS

Medifactia AB and all users of the Tool shall not represent, market, or describe the Tool as:

- diagnostic software or a diagnostic tool;
- therapeutic software;
- artificial intelligence or AI-driven software;
- a medical device.

The Tool is a calculation aid. Users must not rely on Tool output as the sole basis for any clinical decision; clinical responsibility remains entirely with the treating clinician.

The Tool is designed for use within the intended purpose described in this Agreement. Use outside this intended purpose is not supported, may affect the reliability of the Tool´s output, and may constitute a breach of this Agreement. This includes:

- use in pediatric populations (individuals under 18 years of age), as the Tool´s normative reference values have not been validated for this population;
- use with radiopaque markers other than Medifactia® Transit-Pellets;
- use by individuals who are not qualified healthcare professionals;
- use as a standalone diagnostic tool or as a substitute for clinical evaluation.

6. INFORMATION DISCLAIMER

The Tool is provided as a calculation and reporting aid only. Medifactia does not provide medical advice of any kind. While Medifactia uses reasonable efforts to ensure that the Tool functions accurately, Medifactia makes no warranties or representations as to the accuracy, completeness, suitability, or fitness for purpose of any output generated by the Tool.

Medifactia reserves the right to make changes, corrections, and/or improvements to the Tool at any time without notice. Medifactia assumes no liability or responsibility for any errors or omissions. ALL OUTPUT IS PROVIDED “AS IS”. ANY ACTIONS TAKEN BASED ON OUTPUT FROM THE TOOL ARE TAKEN AT THE USER'S SOLE RISK. THE CLINICIAN MUST ALWAYS INDEPENDENTLY VERIFY ANY RESULT BEFORE RELYING ON IT IN A CLINICAL CONTEXT.

NEITHER MEDIFACTIA, NOR ANY OTHER PARTY INVOLVED IN CREATING, PRODUCING, OR DELIVERING THE TOOL SHALL BE LIABLE FOR ANY DIRECT, INCIDENTAL, CONSEQUENTIAL, INDIRECT, OR PUNITIVE DAMAGES ARISING OUT OF THE ACCESS TO, USE OF, OR INABILITY TO USE THE TOOL, OR ANY ERRORS OR OMISSIONS IN ITS OUTPUT.

Medifactia is not liable for loss of data, defects caused by the user, or any personal injury or other consequences resulting directly or indirectly from use or misuse of the Tool. Medifactia's liability in all events is limited to compensation for proven direct losses, up to a maximum of twelve thousand (12,000) Swedish kronor (SEK). Medifactia is not liable for consequential damages, loss of profits, loss of savings, or indirect damages.

The Tool has not been submitted for regulatory clearance or approval as a medical device and is not CE-marked or FDA-cleared as a medical device. It is positioned as a calculation and reporting aid that falls outside the definition of a medical device under EU MDR 2017/745 and applicable FDA regulations.

7. TECHNOLOGY AND SUPPORT

Medifactia does not warrant that the Tool will function with all computing devices or be compatible with all hardware or software configurations. Information is transmitted over networks beyond Medifactia's control; multiple factors, including network availability, may affect operation.

Medifactia, its licensors, and suppliers make no representations or warranties about the availability, accuracy, reliability, completeness, performance, or suitability of the Tool. Although Medifactia takes reasonable measures to keep the Tool free of malicious code, Medifactia does not guarantee that the Tool or any downloadable files will be free of viruses or other harmful components.

8. USER'S RESPONSIBILITIES

The Tool is designed to assist qualified healthcare professionals in calculating and reporting patients' colonic transit time. You are responsible for all data you enter when using the Tool. You are solely responsible for independently verifying all output, for any clinical decisions or actions taken based on Tool output, and for ensuring appropriate clinical indication, diagnosis, and patient management.

You further agree that you will not:

- reproduce, duplicate, copy, sell, resell, or exploit the Tool, its content, its software, or any portion thereof;
- use the Tool for any purpose in violation of local, national, or international laws or regulations;
- upload or register false, misleading, or inaccurate information, including medical, healthcare, or patient identification data;
- upload or transmit any content that is defamatory, obscene, or offensive;
- interfere with or disrupt the proper working or security of the Tool.

Non-enforcement of any provision of this Agreement does not constitute a waiver. Medifactia reserves the right to enforce any term at its sole discretion.

9. LICENCE GRANT

Medifactia grants you a limited, non-exclusive, non-assignable, non-sublicensable licence to access and use the Tool and any related documentation, subject to the terms of this Agreement. This licence is for your personal, non-commercial professional use only and only for the term of this Agreement. You are permitted to download copies of generated reports for personal, non-commercial use only.

10. OWNERSHIP

Medifactia and its licensors own the Tool, including all material and content made available through it, including any proprietary algorithms, and all worldwide intellectual property rights therein. Except as expressly permitted herein, you may not copy, further develop, reproduce, republish, modify, alter, download, post, broadcast, transmit, or otherwise use any material from the Tool. You will not remove, alter, or conceal any copyright, trademark, or other proprietary notices incorporated in the Tool.

11. INFRINGEMENT

Medifactia accepts no responsibility or liability for any data registered by a user at their sole discretion.

12. ENTIRE AGREEMENT

This Agreement constitutes the entire agreement between you and Medifactia pertaining to the subject matter hereof. Anything inconsistent with or conflicting with the terms of this Agreement is superseded by this Agreement. This Agreement may not be modified except as described herein, and may be superseded by terms agreed individually between a user and Medifactia.

13. SEVERABILITY

If any provision of this Agreement is held unenforceable by a court or tribunal of competent jurisdiction, that provision shall be amended or limited to the minimum extent necessary so that the remainder of the Agreement continues in full force and effect.

14. MISCELLANEOUS

Medifactia is entitled to retain subcontractors to perform its obligations under this Agreement.

15. DISPUTES

Disputes arising out of this Agreement shall be finally resolved by arbitration in accordance with the Rules for Expedited Arbitrations of the Arbitration Institute of the Stockholm Chamber of Commerce. The arbitration panel shall consist of one arbitrator. The arbitration shall take place in Gothenburg, Sweden. The proceedings may be conducted in Swedish or English as agreed by the parties. Swedish domestic law, without reference to choice of law principles, shall apply.

16. CONTACTING US

All notices to Medifactia relating to the Tool and/or this Agreement may be made by email to ctt@transit-pellets.com or in writing to:

Medifactia AB
Kungsgatan 60
111 22 Stockholm
Sweden