Ref. No.: SPIU/08040/080726/00
Date: 8 July 2026

STATEMENT ON PRODUCT INTENDED USE
Disposable Mid-Stream Urine Sampler (REF 08040)

1. Product Intended Use

The CURAS® Disposable Mid-Stream Urine Sampler (REF 08040) is a single-use, non-sterile medical device intended for the hygienic collection of fresh mid-stream urine specimens for subsequent laboratory analysis, including urinalysis, urine chemistry and urine microscopy.

The device is designed solely as a temporary urine collection aid. Following specimen collection, the urine should be transferred promptly into an appropriate laboratory specimen container in accordance with the product Instructions for Use (IFU) and the healthcare facility's established procedures. Under the intended conditions of use, the short contact time limits the opportunity for the collection device to influence the specimen prior to analysis. Furthermore, microbial proliferation requires sufficient time, moisture, nutrients, and suitable environmental conditions. Prompt specimen transfer therefore supports preservation of the original specimen characteristics while minimizing the risk of environmental contamination during handling.

2. Hygienic Quality

The hygienic quality of REF 08040 is supported by the following:

A. Controlled Manufacturing Process

Although manufactured from 100% recycled pulp, the raw material undergoes a controlled manufacturing process before becoming a finished medical device. During production, the recycled paper is converted into a pulp slurry, moulded into its final form, and subjected to drying and pressing at temperatures of up to 150°C. This high-temperature process significantly reduces the microbial load. Following manufacture, the finished product is maintained in a dry condition and protected within its original WardPak™ packaging until use.

B. Routine Bioburden Testing

CURAS performs routine microbiological monitoring of the finished product, including Total Plate Count (TPC), Yeast & Mould, and Coliform testing.

Routine bioburden testing of REF 08040 demonstrated **Not Detected (ND) <10 CFU/50 cm²** for the tested microorganisms. These results indicate that no measurable bacterial, yeast, mould, or coliform contamination was detected within the validated laboratory detection limits, demonstrating a very low microbial burden on the finished product.

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C. Storage Conditions

The product should be stored in a clean, dry environment and protected from moisture, excessive humidity, direct sunlight, and physical damage. It should remain in its original WardPak™ packaging until use.

Any product or packaging showing evidence of moisture exposure, fungal growth, contamination, damage, or physical deterioration should be considered compromised and must not be used.

3. Drug and Forensic Testing

Drug and forensic urine testing involves the detection of trace concentrations of specific chemical analytes using highly sensitive analytical methods, including immunoassays and confirmatory techniques.

Compatibility of a urine collection device with these specialized analytical methods should be demonstrated through dedicated analytical validation studies specific to the testing methodology employed.

CURAS has not conducted analytical validation studies to evaluate whether the moulded pulp material of REF 08040 may influence individual drug testing methodologies. Accordingly, CURAS makes no claim regarding compatibility with narcotics, drugs-of-abuse, forensic toxicology, or other specialized analytical testing, nor can it confirm compatibility with all analytical methods used by different laboratories.

This limitation reflects the absence of method-specific analytical validation and should not be interpreted as evidence that the device contaminates or interferes with urine specimens during its intended use.

4. Summary

REF 08040 is intended to support the hygienic collection of fresh urine specimens for routine laboratory analysis when used in accordance with the Instructions for Use. Following collection, the urine specimen should be transferred promptly into an appropriate laboratory specimen container following collection.

The device is supplied as a **non-sterile**, single-use medical device and is intended solely as a temporary urine collection aid. It is not intended to preserve, stabilize, store, transport, or serve as the laboratory specimen container.

For narcotics, drugs-of-abuse, forensic toxicology, or other specialized analytical testing, laboratories should follow their validated specimen collection procedures and use collection devices that have been specifically validated for compatibility with the analytical methods employed.

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Disclaimer

- The product is designed and intended for the collection of fresh urine specimens for subsequent laboratory analysis as described above. Product performance is dependent upon proper storage, handling, specimen collection and use in accordance with the applicable Instructions for Use (IFU). CURAS does not warrant product performance where the device is used outside its intended purpose or contrary to the IFU.
- This Technical Statement is provided for general product information and guidance only. It should be read in conjunction with the applicable Instructions for Use and does not replace professional medical, clinical, or laboratory judgment. Healthcare professionals remain responsible for determining the suitability of the device for each intended clinical application.
- To the extent permitted by applicable law, CURAS shall not be liable for any direct, indirect, incidental, special, or consequential loss or damage arising from misuse, reuse, modification of the product, improper storage, failure to follow the Instructions for Use, or use outside the device's intended purpose.
- Any claim relating to product performance should be supported by documented evidence demonstrating that the device was stored, handled, and used in accordance with the applicable Instructions for Use and the healthcare facility's established procedures.

Reporting and Contact Information

- Any serious incident or adverse event associated with the use of this device should be reported to CURAS and the relevant competent authority in accordance with applicable regulatory requirements, including Article 87 of the European Medical Device Regulation (EU) 2017/745 (where applicable).
- For enquiries regarding this Technical Statement, the applicable Instructions for Use, or product performance, please contact E-mail: info@curas.com

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