

ANNEX – C
NWIP – Bovine Endometrium Cytotaping Catheter
(Item 4.1)

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| Proposed title of Standard | BOVINE ENDOMETRIUM CYTOTAPING CATHETER |
| Aspect | Product Specification |
| Define subject of the standard | Endometritis, one of the most prevalent reproductive problems in cattle, is difficult to be diagnosed. Failure to do so is continuously leading to reproductive wastage and economic losses. Diagnosis of endometritis is widely based on the physical appearance of the discharge, which unfortunately can be erroneous. Hence, the developments in endometritis diagnosis in large animals have focused on detection of endometrial polymorphonuclear cells. The extent of presence of latter in the endometrial impressions has been used in defining both the presence and severity of uterine infections. The available options detecting the endometrial polymorphonuclear cells are marred by several limitations. Accordingly, the proposed stainless steel catheter, tested clinically in the diseased and healthy subjects, promises an easy use, proves to be safe, economical, can be easily fabricated and provides efficient and repeatable results in detecting different grades of endometritis in cows. |
| Scope of proposed standard | Widespread application to circumvent uterine infection related infertility in cows. The same can also be extrapolated into the situations demanding its use in buffaloes as well. |
| Purpose and Justification | Purpose-Endometritis diagnosis, widely based on the physical appearance of the discharge, can be seriously erroneous. For instance, presence of turbid genital discharge reflects endometritis in some, but may be a physiological elimination of the genital microbiome in other cows. Resultantly, some percentages of cows are mis-diagnosed and unnecessarily treated. On the other hand, a low grade of infection, not reflected in the genital discharge, goes unnoticed without any basis of treatment. Justification-Detection of polymorphonuclear cells in the uterine endometrium have been used in endometritis diagnosis. Initially cytobrush and subsequently a cytotope assembly have been used to fulfill the objective. Cytobrush renders bloody and of low quality smears. The latter limitations have been overcome using cytotope. However, the cytotope assembly in practice is sophisticated, expensive and needs to be imported, thereby limiting its widespread application, hence the present proposal. |
| Likely users of standards and their inputs | The proposed standard proves to be highly feasible, safe, practicable, least expensive with a promising potential in furnishing endometrial cytological details with a high degree of reliability and repeatability and will be of immense use for all the veterinary professionals practicing large animal reproduction. A prompt and accurate diagnosis using the proposed catheter will be extremely helpful in treatment and will be of an excellent prognostic value in gauging the treatment outcome in cows with |

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| | clinical or sub-clinical endometritis. Hence, it is foreseen that the catheter will have a widespread application can be used by faculty of all veterinary institutes across India and abroad for teaching, research and public outreach services. |
| Any related standards/series of standard/system standard required to make this subject standard complete | The relevant standard covering the corrosion resistance stainless steel bars and flats, used in the present catheter, have been listed below- Type 304 stainless steel designated as X07Cr18Ni9 in IS 6911 (1992) Stainless steel plate, sheet and strip (MTD 16 Alloy Steels and Forgings). |
| Any specific problem being faced without this standard | Changes in the physical appearance of the genital discharge can be misleading. For instance, presence of turbid genital discharge (clinical endometritis) reflects endometritis in some cows, but may be an indication of physiological elimination of the genital microbiome in others. A cross verification of some of the subjects using the proposed catheter has revealed absence of endometritis and have been subjected to treatments for conditions other than endometritis. Hence, it can be extrapolated that a huge percentages of cows are being mis-diagnosed and unnecessarily being treated for endometritis. In addition, the proposed catheter is proving highly efficient in detecting a low grade of infection, which is not being reflected in the genital discharge. A logical treatment of the latter set of cows has proved to be beneficial in overcoming sub-clinical uterine infections. In nutshell, not using the proposed catheter is hampering a confirmatory diagnosis of endometritis in cows. |
| Bearing with Govt legislation regulation, etc | Not Applicable |
| Name and address of manufacturers/ implementing/ industries/ purchasing organization /component supplier/ raw material supplier, if any | Mayfair Surgical Corporation, Pindi Street Ludhiana, 141 008, Punjab. |
| Status of the industry in the country | Not Applicable |
| Availability of test facilities in the country | Not Applicable |
| Whether related to variety reduction, export, health, safety consumer protection, mass consumption, energy conservation, technology transfer, | The proposed standard has a strong bearing on the animal health and also caters technology transfer, technology up-gradation as mentioned hereunder. Health- Healthy animals are closely related to healthy people and a healthy environment. Animal health is necessary for sustainable livestock production. The animal products do not only represent a source of high-quality food, but are also a source of income for many small farmers and animal |

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| technology upgradation, protection of environment & other National priorities | holders. In the present context, irrational treatment of endometritis in cows, say from antibiotics misuse, besides proving to be a health hazard at the consumers end can also lead to other potential problems such as antimicrobial resistance. Technology transfer or Technology upgradation- The cytotaping assembly being used for endometritis diagnosis is marred with several limitations (point 10). In contrast, the proposed catheter is devoid of all limitations and can be easily replicated and widely adopted |
| Whether subject requires consideration to be given to women/girl issues in line with Sustainable Goal 5 of the UN. If so, whether the issues are proposed to be addressed suitably in the proposed standard | Not Applicable |
| Relevant supportive document (download docs) | After conceptualization, the proposed catheter was fabricated (point 16 of this document). Use of proposed catheter in diseased and healthy subjects has been promising (Please refer to Annexure 1) |
| R & D work done in India | As listed in Annexure 1, no related work to the proposed standard has been cited in the available literature. |
| Any foreign collaboration (give details) | No |
| Liaison with any organisation(s) | No |
| Preparatory work | draft attached |
| Preparatory work (Details) | A preliminary cytoaping catheter was designed which, however, had 3 conspicuous limitations that have been overcome in the proposed standard (Preparatory work at Annexure 1). |
| Whether this project can be funded by your organization | Not required |
| Whether your organisation would be interested to opt for BIS Standard Mark once the standard is published? | Yes |
| Any Other Attachment (extra) | Details of the configuration of the proposed catheter (Annexure 2) |

