1. **Title of Programme(s):**
   (incl. Award Type and Specify Embedded Exit Awards)
   MSc in International Medical Technologies, Innovation and Development

2. **NFQ Level(s)/No. ECTS:**
   9
   90 ECTS

3. **Duration:**
   1.5 years

4. **ISCED Code:**
   0914

5. **School / Centre:**
   School of Science and Computing

6. **Department:**
   Department of Sport, Exercise & Nutrition Science

7. **Type of Review:**
   New Programme

8. **Date of Review:**
   8th June 2021

9. **Delivery Mode:**
   Blended

10. **Panel Members:**
    Mr David Denieffe, Registrar and Vice-President, Academic Affairs at IT Carlow, (Chair)
    Prof Brendan Duffy, CREST Gateway Manager, TU Dublin
    Prof Christof Karmonik, Associate Research Professor of Translational Imaging, Academic Institute, Associate Research Member & Director, MRI Core, Research Institute Houston Methodist
    Ms Marie McCarthy, Senior Director of Product Innovation, ICON
    Ms Carmel Brennan, Head of Academic Quality GMIT (Secretary)

11. **Proposing Staff:**
    Dr Des Foley
    Mr Eugene McCarthy
    Ms Carmel McGrath
    Dr Sharon White
    Dr Patrick Delassus
    Ms Olivia Odhiambo
12. **Programme Rationale:**

Medical Technology is characterised by a constant flow of innovations, which are the result of a high level of research and development within the industry, and of close cooperation with users. Medical technology products typically have a lifecycle of only 18-24 months before an improved product becomes available. In 2019, nearly 14,000 patent applications were filed with the European Patent Office (EPO) (Patent Index 2019) reflecting the high level of innovation activity in the sector. The European medical technology industry is made up of 32,000+ companies, with 95% classified as small to medium-sized enterprises, employing directly more than 730,000 people (MedTech Europe, National Associations survey 2019). The European medical technology market was estimated at roughly €120 billion in 2018 and the Research Priority Steering Group report issued by Government in 2018 highlighted medical technologies as a key priority area that offers the greatest potential for economic return to the state. Ireland is one of the top five emerging global hubs for medical technologies in the world, contributing to over €12 billion in exports annually. Ireland has the highest number of medical technology employees per capita in Europe with over 450 companies operating in this sector nationally employing directly 40,000+ people in 2019 (MedTech Europe, National Associations Survey).

The Galway region supports one of the world’s leading MedTech clusters within 5Km of GMIT’s main campus. Galway’s vibrant ecosystem is made up of a blend of medical technology start-ups, multinationals, research centres and innovation hubs/districts. Core to driving the success of Galway medical technologies' ecosystem is the high level of research and innovation activity both within companies/academia and the innovation partnerships between enterprise and academic research centres funded through state agencies such as Enterprise Ireland and SFI. The MedTech innovation cycle is primarily led by MNCs or start-ups identifying an unmet clinical need or market opportunity. Concepts which are sufficiently innovative and differentiated progress to the development phase. However, a significant risk to advancing technologies in the development phase is the availability of relevant talent and the changing profile of skills needs.

The MSc in International Medical Technologies, Innovation and Development aims to develop the necessary skills required to strategically support the innovation and
development of medical technologies from prototype to pre-clinical phase. Learners will not alone develop critical research skills but will also understand regulatory requirements for each international market for the approval of new medical technologies. Learners will cover advanced pre-clinical evaluation and assessment methods and appreciate their alignment to the business strategy and plans for the marketing of next generation medical technologies. The CEO Masterclass module will enhance learners’ knowledge of intellectual property, commercialisation strategies; research and development funding landscape; reimbursement models and expertise from industry leaders or key opinion leaders on bringing technologies to market.

| 13. Potential Demand for Entry: | It is expected that the profile of the learners enrolled onto the programme will have a relevant level 8 qualification in a health-related science, technology or engineering discipline, preferably with some research and development experience. It is anticipated that the primary target market will focus on employees of medical technology companies, who wish to up-skill or move into a research and development role. The MedTech sector was reported to employ over 40,000 people across 450+ companies (Medtech Europe). From the proposal team’s market analysis approximately 150, primarily start-up and MNC, of these companies have some form of research and development division. Companies operating in this space have expressed an ambition to increase the level of research and innovation and have identified the lack of skills within the company to scale their activity. Based on this information, it is anticipated that the programme will attract between 16-20 learners each year, primarily from the local region. |

| 14. Stakeholder Engagement: | Demand for this proposed programme was initially identified through the Enterprise Ireland funded Medical & Engineering Technology (MET) Gateway. GMIT’s MET Technology Gateway was established in 2016 to deliver innovative solutions to companies operating in the Life Sciences sector. Since 2016, MET has secured €10.6M in funding and delivered 165+ projects for companies developing medical technologies in Ireland. In addition to its national portfolio, MET also works with companies based in the US, Europe, China and India. Key to achieving these targets is the business development team, which includes 3 business development technologists who continually engage with the sector and MET’s industry steering committee who oversee its strategic direction. |
The need for this programme was initially scoped out by profiling the innovative projects undertaken with companies enhancing their technologies from prototype selection to pre-clinical evaluation. Further consultation was carried out with the industry steering group on the 21st of June 2019 and the profile of the data capture was refined to a list of proposed modules.

An extensive consultation with industry partners (Start-ups to MNC’s) committed to developing disruptive life science technologies that address unmet patient needs was carried out in Q1 of 2021. The consultation process was facilitated through a detailed questionnaire followed by one-to-one consultations. Each of the respondents highlighted the need for this programme emphasising its uniqueness to other offerings.

Facilitated through the Galway chamber, consultation on the international needs for the programme were identified through the China-Ireland Health Technology Cooperation conference in 2019. Further consultation in collaboration with GMIT iHubs and Innocare (China based) in 2020 (Q3), on the skills' requirement of the Medical Technology sector further cemented the international needs for such a programme.

| 15. Graduate Demand: | The proposed MSc in International Medical Technologies, Innovation and Development will equip graduates with necessary skills to ensure that future needs of the Medical Technologies sector in the West are met to further enhance the region’s continued reputation as a recognised Life Sciences cluster, a strategic objective of the West Regional Enterprise Plan to 2020. Data collated from the questionnaire and consultation expect graduates to fill roles in the following areas:
- R&D Scientist/Engineer
- Quality/Regulatory
- Design Assurance
- Manufacturing Scientist/Engineer
- Process Development Scientist/Engineer Core Technology Operations Representative |

| 16. Entry Requirements, Access, Transfer & Progression: | A H2.2 Bachelor’s degree at level 8 in any cognate discipline or equivalent in science, technology or engineering, is the minimum entry requirement for this programme. |
English Language Requirements will be as determined by GMIT and as published in the Access, Transfer and Progression code.

GMIT is committed to the principles of transparency, equity and fairness in recognition of prior learning (RPL) and to the principle of valuing all learning regardless of the mode or place of its acquisition. For applicants without this qualification, the RPL process of GMIT will be used to determine admission to the programme. Academic Code of Practice No. 6 outlines the policies and procedures for the Recognition of Prior Learning and guidance for applicants is provided on myexperience.ie

| 17. Programme Structure: | The proposed programme is multidisciplinary by nature and will cover a range of subjects to facilitate the convergence in medical technologies. Module content will contain emerging strategies for the evaluation of medical technologies and will be based on expert advice of the proposal team and best industry practice to satisfy the regulatory bodies for various target markets.

The structure of the programme reflects the success of the Medical & Engineering Technologies Gateway in delivering innovative solutions to industry and the working relationship across 3 schools in GMIT i.e. School of Business, School of Engineering and School of Science and Computing.

The programme consists of a number of 5 and 10 ECTS taught modules delivered over the first two semesters and a substantial research project delivered over semester 2 and 3. |

| 18. Learning, Teaching & Assessment Strategies: | A variety of teaching modalities will be used including:

- Blended learning: Lectures (live online and recorded): provided by academic & research staff, industry.
- Seminars/workshops/networking events: a session in which a specific topic fitting the scope of the course is discussed by an expert in the field.
- Practical exercises: sessions in laboratory facilities in which students get hands-on practical training.
- Research based learning: learning from being actively or passively involved in a research activity.
- Work-based learning: the research project will be conducted in a company or within an applied research centre. Practical elements embedded in the Pre-clinical Evaluation and Assessment module will also contribute to work-based learning. |
Peer review learning will be used to develop skills associated with critical enquiry, reflection, organisation and collaboration. Peer review strategies will be used at research project group meetings, preclinical and evaluations practical and clinical engagement activities and through the networking and workshop activities scheduled for the CEO Masterclass module.

A wide variety of assessment strategies employed will ensure that students with a wide range of learning styles will be facilitated. Assessment methods will include continuous assessments, written technical reports/assignments, oral presentations, statistical analysis and a literature review.

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<tr>
<th>19. Resource Implications:</th>
<th>A full-time member of staff is required to supplement existing capacity to teach this programme. A small number of technical and administrative hours are also proposed to support this programme. This programme will be delivered on a self-financing basis.</th>
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<td>20. Synergies with Existing Programmes:</td>
<td>There is limited overlap with approved postgraduate programmes.</td>
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<td>21. Findings and Recommendations:</td>
<td>General: Commendations: The panel commended the proposers on the development of a programme in this discipline area that is meeting a clearly identified need. The programme is well structured and presented, and the proposers are complimented on the work they have put into progressing the proposal and their positive engagement with the validation panel. The programme was approved subject to the following condition(s) (0) and recommendation(s) (7).</td>
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<td>Special conditions attaching to approval (if any): None.</td>
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### Recommendations of the panel in relation to award sought:

1. Ensure that there are appropriate arrangements in place to ensure confidentiality by and between students in relation to IP issues.
2. Explicitly include patient requirements, the patient voice, patient mapping and the patient journey within the programme content. Patient centricity may be enhanced through the involvement of a patient and IP POSI in the CEO masterclass sessions.
3. Consider including an opportunity for physician interaction during the programme.
4. Clarify the arrangements that will be put in place to ensure that students undertaking project work in MET can be accommodated appropriately. This should include the use of equipment and storage of materials.

### Modules:

5. DESI09009 Medical Technologies: Include smart devices (predictive and diagnostic) and SaMD within this module.
6. STAT09011 Design and Analysis of Experiments: Evaluate on a regular basis the most appropriate tools to use in this module.
7. DESI09010 Design Control and Risk Management: Clarify expectations of MNCs and SMEs in respect of risk.

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<th>22. FAO: Academic Council:</th>
<th>Approved:</th>
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<tbody>
<tr>
<td>Approved subject to recommended changes:</td>
<td>X</td>
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<tr>
<td>Not approved at this time:</td>
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**Signed:**

[Signatures]

|  | Chair | Secretary |