



**Communication and Marketing Department**  
**Isebe loThungelwano neNtengiso**  
**Kommunikasie en Bemerkingsdepartement**

Private Bag X3, Rondebosch 7701, South Africa  
Welgelegen House, Chapel Road Extension, Rosebank, Cape Town  
Tel: +27 (0) 21 650 5427/5428/5674 Fax: +27 (0) 21 650 5628

[www.uct.ac.za](http://www.uct.ac.za)

**25 May 2026**

## **UCT research centre secures SAHPRA licence to manufacture medical devices**

The University of Cape Town's (UCT) Biomedical Engineering Research Centre (BMERC) has officially received its medical device manufacturing licence from the South African Health Products Regulatory Authority (SAHPRA), marking a major milestone for locally developed healthcare innovation.

The licence formally authorises the research centre to conduct manufacturing, distribution and wholesale operations for medical devices for which it holds a registration certificate. The development paves the way for UCT-developed medical technologies to move from research laboratories into clinical use in South Africa.

The director of UCT's BMERC Professor Sudesh Sivarasu said: "In practical terms, it means the devices we design and develop here, for African patients in an African context, can now be produced and brought to market with the full weight of regulatory recognition behind them."

Professor Sivarasu said the problem they set out to solve wasn't simply technical; it was structural.

"South Africa imports the overwhelming majority of its medical devices, which leaves our healthcare system exposed to supply chain shocks and forces our clinicians to work with technologies that were designed, almost without exception, for high-income settings," Professor Sivarasu added.

"At UCT MedTech and BMERC, we have spent more than a decade building one of the most productive academic medical device pipelines on the continent – 23 patent families, five spinout companies and more than 100 000 devices distributed globally. And yet, every promising design hit the same wall: without a certified manufacturing pathway under our own roof, our devices could not be made and used in clinical care here in South Africa.

The licence is a solution to some of the major obstacles previously faced.

"In the medical device sector, quality is synonymous with patient safety; without the ability to demonstrate that our devices were manufactured under a rigorous, audited quality

management system, we could not ethically or legally deploy them with patients. This licence is our solution to that barrier.”

The achievement unlocks:

- Regulatory compliance and market access: BMERC can now formally produce and distribute innovative devices designed for the African healthcare context.
- Validation of quality and safety: the quality management systems have been independently assessed and certified against international standards.
- Innovation and local production: in-house manufacturing reduces reliance on costly imports and supports cost-effective, context-appropriate solutions.
- Training and capacity building: a licenced facility strengthens the ability to train the next generation of biomedical engineers in a real-world, regulatory-compliant environment.

“None of this was the work of any single person. It was built jointly by researchers, students and staff across UCT MedTech and BMERC, and it stands on years of partnership, with SAHPRA; with the [national] Department of Science, Technology and Innovation (DSTI) and the National Research Foundation (NRF) through our South African Research Chairs Initiative (SARChI) Chair in Biomedical Engineering Innovation; with our clinical collaborators across the Western Cape Department of Health; and with our peers across Africa, Asia, North America and Europe. The licence belongs to UCT, but the journey has belonged to many.”

### **Immediate next step**

Sivarasu added: “It has been one of the most transformative undertakings I have been part of at UCT. What began as a compliance project quietly became an institutional capability. The challenges along the way, aligning procedures, interpreting regulatory expectations, building document control habits, embedding risk-based thinking, turned out, in retrospect, to be the curriculum.

“This licence is most visibly aligned with Sustainable Development Goal (SDG) 3, good health and well-being, because every medical device we manufacture under it will be subject to rigorous quality and risk controls that demonstrably improve patient safety, the quality of care and the consistency of clinical outcomes.”

But the reach extends beyond SDG 3.

“It speaks to SDG 9 (industry, innovation and infrastructure), by showing that an African university can host certified medical device manufacturing capacity, not merely import the products of others. It speaks to SDG 4 (quality education), because we are training South Africa’s first cohort of biomedical engineers who graduate already fluent in ISO 13485 and SAHPRA requirements.

“It speaks to SDG 10 (reduced inequalities), through our explicit commitment to appropriate Biodesign, designing devices that work in resource-constrained settings, not only in well-resourced ones. And it speaks to SDG 17 (partnerships for the goals), through the international collaborations across Africa, Asia, Europe and North America that helped us get here and that will scale the impact further.”

He concluded: “The immediate next step is to convert our pipeline of late-stage prototypes into clinically validated, locally manufactured products. With the SAHPRA licence in hand, we can move flagship devices from ‘bench-top’ to ‘bedside’ under our own quality system. Our

goal is that, within the next 18 to 24 months, devices manufactured at UCT's medical school are in routine clinical use in South African public hospitals. This is aligned with our mission to pioneer innovative medtech products, train innovators and build a health technology pipeline for unmet clinical needs, improving the quality and dignity of people's lives."

*Story by Kamva Somdyala, UCT News.*

**Issued by: UCT Communication and Marketing Department**

**Velisile Bukula**

Head: Media Liaison  
Communication and Marketing Department  
University of Cape Town  
Rondebosch  
Tel: 021 650 2149  
Cell: 071 642 3495  
Email: [velisile.bukulai@uct.ac.za](mailto:velisile.bukulai@uct.ac.za)  
Website: [www.uct.ac.za](http://www.uct.ac.za)