YOUR SMILE. OUR VISION.

SDI LIMITED ACN 008 075 581 | ABN 27 008 075 581
HEAD OFFICE 3-15 BRUNSDON STREET, BAYSWATER. PO BOX 314, VICTORIA, 3153 AUSTRALIA.
TOLL FREE 1800 337 003 | **TELEPHONE** +61 3 8727 7111
FAX +61 3 8727 7222 | info@sdi.com.au | www.sdi.com.au

ASX Announcement

23 April 2024

EU MDR Certification

MELBOURNE, Australia – SDI Limited (ASX: SDI) announced today that it has successfully secured its certification under the European Union's Medical Device Regulation 2017/745 (MDR) as a manufacturer. SDI will still be able to continue selling existing products into all European markets as planned and without interruption under the EU MDR Transition Extension.

This also included MDR product certification of SDI's latest new product Stela. Stela was originally designed as an Amalgam replacement product but is also used for many indications and will compete in the wider Aesthetic categories due to its natural tooth colour and strength. Stela is now registered in most of SDI's key markets.

SDI's Chief Executive Officer Samantha Cheetham said " *The EU MDR represents a significant enhancement over the previous Medical Device Directive (MDD), emphasising improved safety measures, risk management, post-market surveillance, and data collection for medical devices. This milestone is a testament to the collaborative efforts of the team at SDI, underscoring our continued commitment to the quality, safety, and effectiveness of our products.*

The MDR certification marks a pivotal step in SDI's ongoing expansion within the European market, supporting growth through both existing and new products. Europe is SDI's largest market, and the launch is planned for July. Stela will become SDI's largest Composite product and the opportunities are significant."

This announcement has been authorised by the Board of Directors of SDI Limited.

Investor Contact:
Adrian Mulcahy
adrian.mulcahy@automicgroup.com.au
P: +61 438 630 422